The development and preliminary evaluation of a measure to improve assessment and management of symptoms and concerns of people with dementia in residential care homes

Ellis-Smith, Alexandra Clare

Awarding institution:
King's College London

THE DEVELOPMENT AND PRELIMINARY EVALUATION OF A MEASURE TO IMPROVE ASSESSMENT AND MANAGEMENT OF SYMPTOMS AND CONCERNS OF PEOPLE WITH DEMENTIA IN RESIDENTIAL CARE HOMES

A thesis incorporating publications submitted to

King's College London for the degree of Doctor of Philosophy

Alexandra Clare Ellis-Smith BSc (OccTher) MSc

Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation

Faculty of Life Sciences and Medicine, King's College London

April 2018

Personal contribution and declaration of originality

This study was conducted while I was working at Cicely Saunders Institute, King's College London and was conducted by me, with supervision from Dr Catherine Evans, Professor Irene Higginson and Dr Barbara Daveson.

I conceived of the study aims and objectives, developed the overall study design, and conducted all aspects of the study, including obtaining ethical and research governance approvals, developing all study materials, conducting all the focus interviews and interviews, and analysing and interpreting the data. The thesis was written by me and represents my own original thoughts and ideas. I was supported throughout by my supervisors.

I received study support from a research nurse in recruitment and consent. This included help in running coffee mornings, meeting with potential participants - including residents, family members, care home staff and health care professionals - to explain the study, and obtaining informed consent. The research nurse also assisted in case note data extraction, and assisted in focus groups by making observations and writing field notes. Administrative support was received for transcription of interviews and focus groups. The Clinical Research Network South London supported the study in providing a nominated consultee.

A PPI member and service user and carer advisory group supported the study through advising on the study aims and methods, assistance in developing the study materials and refining the intervention. In addition, the wider POS development team informed decisions regarding the development and refinement of the intervention based on the study findings.

The following are specific contributions by each author (author initials) for each of the publications incorporated into the thesis.

Paper 1: Authors' contributions: CES, CJE, IJH and BAD conceived and designed the study. CES conducted the literature search, CES, CJE, AEB, LAH, MD, PMK and BAD were involved in the analysis and interpretation of the data. CES, CJE, IJH and BAD drafted the manuscript. The study was supervised by CJE, IJH and BAD. All authors read and approved the final manuscript.

Paper 2: Authors' contributions: CES, CJE, IJH and BAD conceived and designed the study. CES and LAH collected the data. CES, CJE, IJH, BAD were involved in the analysis of the data and CES, CJE, IJH, BAD, FEMM and AMF were involved in the interpretation of the data. CES, CJE, IJH and BAD drafted the manuscript. The study was supervised by CJE, IJH and BAD. All authors read and approved the final manuscript.

Paper 3: Authors' contributions: CES, IJH, BAD and CJE conceived and designed the study. CES and LAH collected the data. CES, IJH, BAD and CJE were involved in the analysis and interpretation of data. CES, IJH and CJE drafted the manuscript. The study was supervised by CJE BAD and IJH. All authors read and reviewed the final manuscript.

Abstract

Background

People with dementia living in residential care homes often experience multiple symptoms and concerns associated with dementia and co-morbidities. As dementia progresses, individuals may experience increasing difficulties expressing their wishes and concerns. The complexity of symptom presentation and declining communication mean the assessment and management of symptoms and concerns is often challenging. Poor detection results in symptoms and concerns being untreated, increasing distress and compromising quality of life. A systematic review identified no comprehensive measure to support assessment and management of symptoms and concerns by care home staff for people with dementia.

Aim

To develop and then conduct a preliminary evaluation of the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem) to improve assessment and management of symptoms and concerns for people with dementia in residential care homes.

Methods

Design: A three-phase mixed methods study informed by the Medical Research Council guidance for developing and evaluating complex interventions. The study was underpinned by a theoretical model of the expected mechanisms of action of a measure used in routine care to improve assessment and management of symptoms and concerns.

Setting and participants: Three residential care homes in a borough in South London. Participants were people with dementia/cognitive impairment in residential care homes, their family members, care home staff, and health care professionals including general practitioners and district nurses.

Pre-clinical scoping review phase: A systematic scoping review of the literature to identify common symptoms and concerns experienced by people with dementia to develop IPOS-Dem Version 1, adapted from the Integrated Palliative care Outcome Scale (IPOS).

Development phase: A qualitative phase comprising focus groups and semi-structured interviews with family members, care home staff, and health care professionals to explore content validity, expected mechanisms of action, acceptability, feasibility, and implementation requirements of IPOS-Dem used in routine care of people with dementia in the care home context. Followed by

cognitive interviews to determine the acceptability and ease of comprehension of IPOS-Dem to care home staff.

Evaluation phase: A qualitative study with embedded quantitative component. IPOS-Dem was implemented in routine care of people with cognitive impairment in residential care homes. Qualitative data collection comprised focus groups and semi-structured interviews with family members, care home staff, and health care professionals, and non-participation observations of health care professional consultations with care home staff to explore the mechanisms of action, acceptability, feasibility, and implementation requirements of IPOS-Dem in the care home context. Quantitative data comprised IPOS-Dem scores at baseline and final time point at 12 weeks. Qualitative data were analysed using directed content analysis and quantitative using descriptive statistics. Qualitative and quantitative data were analysed separately and then integrated on key areas to inform the final theoretical model.

Results

Pre-clinical scoping review phase: Five additional items were identified and five existing IPOS items were amended to reflect symptoms and concerns experienced by people with dementia and multi-morbidities, resulting in IPOS-Dem Version 1.

Development phase: Six family members and 20 care home staff and health care professionals participated in focus groups (n=4) or semi-structured interviews (n=3). Ten care home staff participated in cognitive interviews. Five additional symptoms and concerns to ensure comprehensive assessment were identified resulting in Version 2. Refinements from cognitive interviews included the use of lay terms and item descriptors and formed Version 3. The development phase output was IPOS-Dem Version 3 with a pre-implementation understanding of the care home context, likely mechanisms of action, acceptability, feasibility, and implementation requirements ready for the evaluation phase.

Evaluation phase: Thirty-two residents with cognitive impairment received IPOS-Dem as part of routine care with 30 completing the full 12 weeks evaluation. Seven family members, and 11 care home staff and health care professionals participated in focus groups (n=2), semi-structured interviews (n=7), and/or non-participant observations (n=3). Findings informed a theoretical model to demonstrate the key mechanisms of action and potential benefit, measurement properties, and implementation requirements. Mechanisms of action included, for example, improved observation and awareness of residents, comprehensive ‘picture of the person’, and facilitated

communication. Potential benefit was improved symptom management and comprehensive care, and increased family empowerment and engagement. IPOS-Dem was acceptable and feasible, with participants reporting that it supported care processes and was quick and easy to use. Missing data decreased from 2.1% at baseline to 1.1% at final time point. Leadership was essential in implementing IPOS-Dem into routine care processes.

Conclusion

IPOS-Dem addresses a gap in the comprehensive assessment and management of symptoms and concerns experienced by people with dementia in care homes. It incorporates key symptoms and concerns that older people with dementia and multi-morbidities, and their family members may experience; and is developed for care home staff knowledge, skills and remit within the care home context. It is acceptable and feasible for use in routine care, and may improve care processes resulting in potential benefit to people with dementia and their family members. IPOS-Dem is now ready for future research on the psychometric properties and a feasibility trial to test the methods for a full trial of effectiveness on improving care outcomes.

Table of contents

Table of contents

Table of figures

List of tables

Publications, presentations and awards

Publications in peer reviewed journals

The following publications have been incorporated into chapters in the thesis:

Ellis-Smith C, Evans CJ, Bone AE, Henson LA, Dzingina M, Kane PM, Higginson IJ, Daveson (2016). Measures to assess commonly experienced symptoms for people with dementia in long-term care settings: a systematic review. *BMC Medicine* 14(1): 38. doi: 10.1186/s12916-016-0582-x **[CHAPTER 2]**.

Ellis-Smith C, Evans CJ, Murtagh FE, Henson LA, Firth AM, Higginson IJ, Daveson BA (2017). Development of a caregiver-reported measure to support systematic assessment of people with dementia in long-term care: The Integrated Palliative care Outcome Scale for Dementia. *Palliative Medicine* 31(7):651-60 **[CHAPTER 6]**.

Ellis-Smith C, Higginson IJ, Daveson BA, Henson LA, Evans CJ. How can a measure improve assessment and management of symptoms and concerns for people with dementia in care homes? A mixed-methods feasiblity and process evaluation of IPOS-Dem. Manuscript submitted to PLOS One, under review **[CHAPTER 7]**.

Presentations and published abstracts

Ellis-Smith C, Evans CJ, Higginson IJ, Daveson BA. The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes. First annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; November 2013; London, UK.

[Poster presentation]

Ellis-Smith C, Evans CJ, Higginson IJ, Daveson BA. A protocol for the development of the Palliative care Outcome Scale for Dementia (POS-Dem) (2014). *Palliative Medicine* 28(6), 895

[Published abstract]

Ellis-Smith C, Evans CJ, Higginson IJ, Pannell C, Henson LA, Daveson BA. The content validity and utility of an assessment tool to improve detection of symptoms and problems experienced by people with dementia in care homes: The Palliative care Outcome Scale for Dementia – Assessment (POS-DemA). Second annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; November 2014; London, UK.

[Poster presentation]

Ellis-Smith C, Evans CJ, Higginson IJ, Pannell C, Henson LA and Daveson BA. The content validity and utility of a screening tool to improve detection of problems, care provision and healthcare access for people with dementia in residential care homes: The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA). 14th World Congress of the European Association for Palliative Care. Copenhagen, Denmark, May 2015.

[Published abstract and poster presentation]

Ellis-Smith C, Evans CJ, Murtagh FEM, Henson LA, Firth AM, Higginson IJ, Daveson BA. Development of a caregiver-reported measure to support systematic assessment of people with dementia in long-term care: the Palliative care Outcome Scale for Dementia – Assessment (POS-DemA). Third annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; March 2016; London, UK.

[Poster presentation]

Ellis-Smith C, Evans CJ, Bone AE, Henson LA, Dzingina M, Kane PM, Higginson IJ, Daveson. Measure to assess commonly experienced symptoms for people with dementia in long-term care settings: a systematic review. Third annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; March 2016; London, UK. [Oral presentation]

Ellis-Smith C, Evans CJ, Higginson IJ, Murtagh FEM, Firth AM, Daveson BA. A measure to support systematic assessment of people with dementia in care homes: the Palliative care Outcome Scale (POS) for Dementia – Assessment (POS-DemA) (2016). *Palliative Medicine* 30(6): NP1-NP401, doi:10.1177/0269216316646056
[Published abstract and poster presentation]

Ellis-Smith C, Evans CJ, Bone AE, Henson LA, Dzingina M, Kane PM, Higginson IJ, Daveson. Measures to assess commonly experienced symptoms for people with dementia in long-term care settings: a systematic review (2016). *Palliative Medicine* 30(6): NP1-NP401, doi:10.1177/0269216316646056
[Published abstract and poster presentation]

Ellis-Smith C, Higginson IJ, Daveson BA, Henson LA, Evans CJ. What are the mechanisms of action to improve assessment in care homes for people with dementia: a qualitative study of family and professional caregivers before and after implementation? 15th World Congress of the Association for Palliative Care. Madrid, Spain, May 2017.
[Published abstract and poster presentation]

Ellis-Smith C, Higginson IJ and Evans CJ. Development and preliminary evaluation of a caregiver-reported measure to improve assessment and management of symptoms and concerns of people with dementia in care homes: the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem). Biology of Ageing: impactful interventions. Singapore, November 2017 [Poster presentation]

Awards and prizes

Ellis-Smith C, Evans CJ, Murtagh FEM, Henson LA, Firth AM, Higginson IJ, Daveson BA. Development of a caregiver-reported measure to support systematic assessment of people with dementia in long-term care: the Palliative care Outcome Scale for Dementia – Assessment (POS-DemA). Third annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; March 2016; London, UK.
Winner of best poster presentation.

Ageing Research at King's/King's College London graduate school PhD Travel Award to attend Biology of Ageing: Impactful Interventions conference in Singapore. 2017.

Acknowledgements

I would first like to thank the residents who participated in this study without whom this study would not have been possible. Thank you too to the family members, care home staff, and health care professionals who so generously gave their time and whose insights were invaluable.

Thank you to my PhD supervisors, Dr Catherine Evans, Professor Irene Higginson, and Dr Barbara Daveson for their support, guidance and wisdom; and to my colleagues at the Cicely Saunders Institute for all the help, friendship, and encouragement along the way. I would also like to thank the PPI members who generously gave their time and feedback, and whose continued involvement undoubtedly strengthened the study.

I would like to acknowledge Cicely Saunders International and The Atlantic Philanthropies for funding this PhD fellowship as part of the BuildCARE (Building Capacity, Rights and Empowerment) project. I am very grateful for the opportunity it afforded me and for making this study possible. Thank you too for the support from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London.

Finally, thank you to my family and friends for their patience, love, and encouragement; and particularly to my partner, Richard, for his unstinting support and being there for me throughout the PhD.

Glossary of terms

Care homes- 24-hour staffed accommodation providing care to people who are no longer able to live independently and who may require support during the day and night (1).

Nursing homes- care homes registered to provide nursing care and staffed with 24-hour onsite registered nursing staff for people who may have nursing needs (1).

Residential care homes- care homes registered to provide residential care with no requirement for onsite registered nursing staff (1).

Complex interventions- Complex interventions are defined by a number of characteristics: they may have a number of different components that may interact, may require behaviour changes, may be directed at multiple groups, have multiple outcomes, and may vary in the degree of flexibility of delivery (2).

Context- Context is anything external to the intervention, which may either impede or assist implementation or its consequences (3).

Feasibility study- a study which occurs prior to a full trial of effectiveness and which provides the opportunity to examine components of the intervention (such as acceptability, feasibility), and aspects of the testing procedures (such as recruitment and retention and effect size) (2). Feasibility testing may also provide valuable insights and understanding of the context of intervention delivery (4).

Implementation- 'the process through which interventions are delivered, and what is delivered in practice', including what is delivered and how it is delivered (5).

Implementation requirements of the intervention- this includes important features of the intervention that maximise its implementation such as training and additional resources, and the mechanisms which may support implementation.

Measures/Outcome measures

Measure- a standardised and validated patient-reported or proxy-reported measure designed to capture concerns important to patients, or in this study, people with dementia living in care homes.

Outcome measure- a standardised and validated measure of change in patient health status as a result of an intervention or health care delivered (6).

Patient-centred outcome measure (PCOM)- Patient-reported or proxy-reported outcome measure that designed to capture concerns important to patients (7).

Patient-reported outcome measure (PROM)- an outcome measure completed by patients to measure their own perspectives of health status, functional status or wellbeing (8).

Proxy-reported outcome measure- an outcome measure to measure concerns important to patients, but not completed by patients usually because they are too unwell or have significant cognitive impairment to self-report (7).

Measurement properties

Validity: the degree to which an instrument measures what it purports to measure (9).

Reliability: 'the degree to which the measurement is free from measurement error' (9).

Responsiveness: the ability of a measure to detect change over time in the construct to be measured (9).

Interpretability: the degree to which one can assign qualitative meaning, or clinical connotations, to a measure's score(s) or change in score(s) (9).

Acceptability: whether patients (for patient-reported measures) or staff/health care professionals are prepared to and willing to use the measure (10), and its suitability for intended use in clinical practice (11).

Comprehension: how patients or staff/health care professionals understand, interpret terms, and choose their responses (10).

Feasibility: whether patients or staff/health care professionals are able to use the measure in their respective setting or context (10).

Availability was added to capture the requirement for measures, and additional training and resources, to be easily and freely accessible (12, 13).

Palliative care- 'an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual' (14).

Process evaluation- 'A study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors. Process evaluation is complementary to, but not a substitute for, high quality outcomes evaluation' (5).

Residents: Residents of nursing or residential homes, with or without dementia. The term 'patients' is not used to represent that this is person's home and not a clinical settings.

Abbreviations

Abbreviation	Meaning
CANE	Camberwell Assessment of Need
CCC	Concordance Correlation Coefficient
CI	Confidence Interval
CMAI	Cohen-Mansfield Agitation Inventory
CQC	Care Quality Commission
CRN SL	Clinical Research Network South London
DCM	Dementia Care Mapping
DeNDRoN	Dementias and Neurodegenerative Diseases
EoLC	End of Life Care
EOLD-CAD	End of Life in Dementia – Comfort Assessment in Dying
EOLD-SM	End of Life in Dementia – Symptom Management
EOLD-SWC	End of Life in Dementia – Satisfaction With Care
EORTC QLQ-C30	European Organisation for Research on Cancer Treatment Quality of Life Questionnaire
DN	District Nurse
ENRICH	Enabling Research in Care Homes
FAST	Functional Assessment Staging
FATE(-S)	Family Assessment of Treatment at the End of life (- Short version)
FPCS	Family Perceptions of Care Scale
FPPFC	Family Perceptions of Physician-Family caregiver Communication
GDS	Global Deterioration Scale
GP	General Practitioner
IPOS	Integrated Palliative care Outcome Scale
IPOS-Dem	Integrated Palliative care Outcome Scale for Dementia
MCA	Mental Capacity Act
MDS	Minimum Data Set
MIDOS	Minimal Documentation system for Palliative care
MORECare	Methods Of Researching End of Life Care
MRC	Medical Research Council
MSSE	Mini Suffering State Examination
NHS	National Health Service
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
POS	Palliative care Outcome Scale
PCOMs	Patient-Centred Outcome Measures
PIC	Participant Identification Centre
PPI	Patient and Public Involvement
PROMs	Patient-Reported Outcome Measures
QUALID	Quality of Life in Late-Stage Dementia
QODD	Quality of Dying and Death
QOD-LTC	Quality of Dying in Long Term Care
QOD-LTC-C	Quality of Dying in Long Term Care – Cognitively Intact
(m)QOLC-E	(modified) Quality of Life Concerns in End of life questionnaire
RAI-PC	Resident Assessment Instrument for Palliative Care
R&D	Research and Development
RCTs	Randomised Controlled Trials
REC	Research Ethics Committee
RGF	Research Governance Framework
SD	Standard Deviation
SMMSE	Standardised Mini-Mental State Examination
STAS	Support Team Assessment Schedule
TIME	Toolkit of Instruments to Measure End of life care
UK	United Kingdom
US	United States
WHO	World Health Organisation

1. Background

1.1 Introduction

Dementia is an international public health priority (15). It is the leading cause of disability and dependency in chronic illnesses (16), and has profound physical, emotional and financial effects on those with the illness, their families and wider society (15). Dementia is progressive and terminal (17, 18), and there is currently no cure nor any treatment to stop its progression (15). As a consequence, the World Health Organisation (WHO) has emphasised the requirement to improve the lives of people with dementia and their families through optimising health and wellbeing, assessing and treating comorbidities and symptoms, and providing information and support to family carers (19). Central to this is improved management of distressing symptoms and concerns experienced by people with dementia and their families (20-22) to improve quality of life and wellbeing.

1.2 Dementia

1.2.1 Epidemiology

Dementia is predominantly a disease of older age (16). The incidence of dementia doubles with every 6.3 year increase in age from 3.9 per 1000 person-years for the age group 60-64 to 104.8 per 1000 person-years for aged 90 years and over (23). Increased life-expectancy is resulting in a global ageing population, which in turn is increasing the prevalence of dementia (24). In 2015, the estimated prevalence was 46.8 million, and this is anticipated to increase 131.5 million by 2050; with an estimated incidence rate of 9.9 million new cases of dementia worldwide each year (23). The median survival from onset of disease has been estimated from between 3.3 to11.7 years, with the majority of studies reporting a median survival of between 7-10 years (25). In 2015, dementia became the leading cause of death in England and Wales accounting for 11.6% of all deaths registered (26). While a recent study conducted to estimate population palliative care need in England and Wales based on past trends (27), projected the expected number of deaths as a result of dementia to rise from 59,199 in 2014 to 219,409 deaths per year in 2040.

1.2.2 Dementia: definition, presentation and disease trajectory

Dementia is a term that describes a group of diagnoses characterised by progressive decline in cognition resulting from neurodegeneration (28). As dementia progresses, all aspects of cognition

are affected including memory, orientation, verbal and nonverbal communication, ability to learn new information, and executive functioning (29). Dementia is staged according the degree of cognitive and functional abilities using measures such as the Standardised Mini-Mental State Examination (SMMSE) (30), Global Deterioration Scale (GDS) (31), or Functional Assessment Staging (FAST) (32). In the early stages of dementia or mild dementia, people may require support for instrumental activities of daily living such as shopping and cooking, and may start to have difficulties with word or name finding (32). Those with moderately severe dementia typically require support with personal activities of daily living including dressing, bathing, and toileting; while severe or advanced stage dementia is characterised by minimal or no verbal communication, urinary and faecal incontinence, inability to walk, and complete dependence in all areas of functioning (32).

People with dementia may also experience psychological symptoms and behaviours that challenge which may cause distress to them and their families, or those close to them. These symptoms may also complicate care provision. They can occur at any stage of the illness trajectory and include, amongst others depression, hallucinations, delusions, aggression, irritability, and wandering (20, 33).

1.2.3 Dementia, multi-morbidity and frailty

Many people with dementia also have other common conditions of older age (34), notably frailty (35). As a consequence of dementia, multi-morbidities, disability, and polypharmacy (36-38), people with dementia may experience high physical symptom burden, and emotional and social concerns. People with advancing dementia may have challenges expressing their wishes and concerns (39, 40) and symptoms and concerns may therefore be undetected and untreated, leading to reduced quality of life and avoidable distress. Distress can manifest as behavioural changes that may challenge, for example aggression, irritability, and wandering, making the provision of care increasingly complex and demanding, and depleting already-stretched resources (41).

1.2.4 Family carers: the impact of dementia and challenges to sustaining the caring role

Complex care needs, high dependency, high symptom burden, and behaviours that challenge place considerable demand on family carers, or those close to the person with dementia. In

addition, the main carer is often a spouse of advanced age who may be living with multi-morbidities themselves (42). The complexity of care needs, and the health and wellbeing of family carers means many people with dementia move into a care home (43), particularly in the advanced stages; with cognitive impairment being a prominent predictor of care home transition (44). In particular, worse cognition, higher dependency, behaviours that challenges, and carer burden all increase the risk of care home transition (43, 45, 46). It is estimated that approximately 36.5% of those with dementia live in care homes increasing from 27.8% of those in those aged 65-74 to 60.8% in those aged 90 and over (47). In 2012-2014, 58% of all deaths of people with dementia occurred in the care home setting (34).

While a move into care homes may increase support for family members, it is also a time of loss; and may result in a different type of carer stress (48). Many family members would like to retain a caring role when a relative moves to a care home (49, 50) but frequently feel excluded from this (48). This can result in a sense of loss, frustrations due to a lack of control, and difficulties adjusting to their change in role (48).

1.2.5 The care home context: residential care homes

Care homes offer 24-hour staffed accommodation and care to people who are no longer able to live independently and who may require support during the day and night (1). The most common reasons for admission to care homes are clinical (48.7%) followed by frailty (28.8%) (51).

There are different types of care homes in the United Kingdom (UK) and internationally, categorised by staffing (52). Care homes in England are registered with the Care Quality Commission (CQC) (1). Type of care home and registration comprise two main types: nursing homes (those with 24-hour onsite registered nursing staff for people who may have nursing needs) and residential care homes (those with no onsite registered nursing staff) (1). Both nursing and residential homes may also be registered to provide care for specific age groups e.g. people 65 years and older, and conditions e.g. dementia (1). Even though there are differences in the staffing requirements and registration, the two types of care home often provide care for similar groups of people with complex care needs. In 2009, Bupa, with the Centre for Policy and Ageing, carried out a census of all their care homes in the UK, Australia, New Zealand, and Spain with a 95% response rate, and incorporating 15,477 care home residents in the UK. The average age

of residential care home residents in the UK was 85.0 (n=3,829) compared to an average of 82.0 (n=11,575) of nursing home residents (51). The most common conditions were similar for residential care home residents (n=3,829) and nursing home residents (n=11,575) comprising: all neurological impairments – including dementia and stroke (65.5% versus 78.3%), incontinence (65.0% versus 77.2%), dementia (40.9% versus 45.0%), arthritis (19.7% versus 18.0%), heart disease (15.6% versus 22.3%), and stroke (11.9 versus 23.1%) (51).

The total number of care home beds in England is over 450,000. The two types of care homes have a similar total bed capacity, but with nursing homes tending to be larger. In 2017 the number of residential care home beds was 239,902 compared to 220,815 nursing home beds in England (53). The number of residential care homes in England registered with the CQC (1) was 10,858 compared to 4,042 nursing homes (53). Residential care homes are typically small (1-10 beds: n-4,408, 41.0%) or medium (11-49 beds, n=5762, 53.1%). Larger residential care homes of 50 beds or more are less common (n=688, 6.3%) (53). The majority care home services in England are predominantly provided by independent organisations (private or voluntary) (54). These organisations are largely responsible for employment, training, pay, and terms and conditions for their employees (54).

The adult care sector in England is under increasing pressure. There is a growing demand for services, with an ageing population and complexity of care needs associated with longevity and commonality of multi-morbidity (27, 55). The increasing demand is further compounded by workforce challenges notably high staff turnover (27.8% in 2016-2017), high staff vacancies (6.6% in 2016-2017), and increasing demand for care exceeding growth in jobs. Workforce challenges relate in particular to care work being perceived as low skilled with limited opportunities for career progression, low pay, and leadership problems with high vacancy rate of managements (11.3% in 2016-2017) (54). In addition, the care sector is under significant financial pressure with the majority of its income from public funding (65%). In the past six years, local authority spending on care has decreased by 5.3% in real terms and is further expected to decrease by 0.2% in the next two years. This, with the increasing demand in care, mean there is a significant spending pressures and a lack of certainty about future funding being sufficient, resulting in further impacts on workforce planning.

The workforce employed in adult residential care homes in England is relatively large (305,000 jobs), and comprises mainly women (83%) with an average age of 43 years (56). Most posts are direct carer jobs (225,000 approximately) (56). Around half the posts are full-time (53%) with the remainder part-time (40%), or with no set hours (8%) (56). The majority of the residential care home workforce in England are British (85% in 2016/2017), and only 15% non-British. However, the proportion of non-British workers in the London region is much higher with 39% being non-British across the adult social care sector in England (57).

Few staff hold a formal social care qualification. In 2017, across the adult social care sector 51% of direct care staff held no social care qualifications. A small proportion held qualifications at level 2 (25%) or level 3 (18%) (58). Around half of direct care staff (57%) in residential care homes complete or partially complete the Care Certificate within two years of moving into the sector. This is lower than in nursing homes (67% of direct care staff) (57). The Care Certificate is predominantly targeted as those new to the care sector and comprises 15 standards, for example, duty of care; equality and diversity; awareness of mental health, dementia and learning disability; and safeguarding adults (59).

Overall, residential care homes face many challenges. They care for a population with increasingly complex care needs, have challenges with workforce recruitment and retention, and most staff members hold no formal training. They are also not required to employ registered nurses (nurses) and therefore rely on community and primary care services to meet residents' health care needs (60, 61). This means that residential care home staff are required to detect and monitor changes in symptoms and concerns, and access health care on the individual's behalf. This is despite the fact that the majority (or frequently all) do not hold a clinical qualification such as nursing.

Access to health care for people living in care homes depends on integrated working between residential care homes and health care providers (60, 62). However, there are barriers to integrated working between these sectors. These include (i) different work cultures, priorities, infrastructures and funding sources; (ii) hierarchies and power dynamics; (iii) poor training opportunity with high staff turnover in care homes (60, 62-65); and (iv) a lack of clearly defined roles (60). In this context, some care home staff may face challenges in communicating and

sharing their assessments of residents with health care professionals. They may not feel listened to or understood by health care professionals, or feel that their skills are not respected (64). Access to specialist health services for people living in care homes compared to those living at home is often inequitable (63, 66-70), including access to palliative care (71).

1.2.6 Palliative care and dementia

Palliative care is defined as,

> 'an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual' (14)

There is international consensus that palliative care, with its aim to improve quality of life through comprehensive and timely assessment, and treatment of distressing symptoms and concerns may benefit people with dementia (22). However, there is a lack of consensus about when in the disease trajectory palliative care should be introduced or provided (22). A goal-directed model of care to address this has therefore been proposed (Figure 1) (22, 72). This model is based on the suggested premise that there are three main goals of providing medical care: 'prolongation of life', 'maintenance of function', and 'maximisation of comfort'. It is proposed that palliative care is most aligned to the goals of 'maintenance of function' and 'maximisation of comfort', which starts at the onset of dementia but increases as dementia progresses (72). Palliative care and arguably all high-quality dementia care aims to improve quality of life (14) and maintained function and living without discomfort are essential components of good quality of life (73, 74). Improving quality of life for people with dementia throughout the disease trajectory is indisputably an essential part of good quality dementia care. It is therefore difficult to argue against an approach that emphasises early and impeccable assessment and treatment of physical, emotional, social and existential concerns, as well as family concerns in this population (14). There is evidence that introducing routine assessment of quality of life into clinical care may improve quality of life in other populations with serious illness, notably cancer (75, 76).

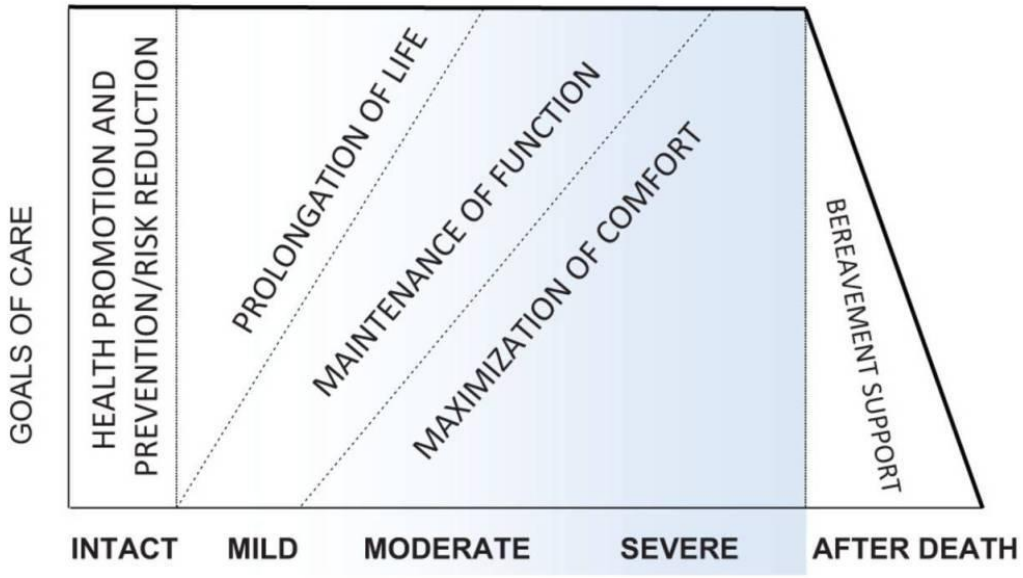


Figure 1 Dementia progression and suggested prioritising of care goals (22)

The projected increase in dementia deaths, the long illness trajectory, and the potential capacity for people with dementia to benefit from palliative care pose a substantial challenge to the palliative care discipline (27). Currently, specialist palliative care does not have the capacity to meet this need, and huge training of specialist palliative care professionals would be required to do so (27). There is therefore an urgent requirement to find a better model of care delivery to meet this need. A possible and more feasible model is for those providing the majority of care to people with dementia, or generalist palliative care providers, to continue to do so with the support of specialist palliative care for more complex patients (77). However, this requires that those providing the majority of care have the necessary skills to assess and manage symptoms and concerns, and access health care services and specialist palliative care services when required. For people with dementia in care homes and residential care homes in particular, those providing the majority of care are care home staff without a clinical qualification. Care home staff are well-placed to assess symptoms and concerns due to their frequent close contact and good knowledge of the residents they care for (78). On the other hand, this means it is essential for them to be able to detect and address symptoms and concerns in a timely way, and access health care to support the treatment and management of distressing symptoms. Given the paucity of evidence-based interventions for this population in this setting (71, 79-81), there is therefore an urgent requirement for interventions that support assessment and management of symptoms and concerns by care home staff without a clinical qualification for this population.

1.3 Measures used in routine care for people with dementia

1.3.1 Patient-reported outcome measures and proxy-reported outcome measures

Patient-reported outcome measures (PROMs) are standardised and validated questionnaires, which are completed by patients to measure their perceptions of their own health status (8). Traditionally designed to measure outcomes as a result of research studies, there is increasing recognition of their potential benefit as an intervention in routine clinical care as a means of improving the provision and outcomes of patient-centred care (7, 11). This is because PROMs intend to measure and capture concerns held by patients, which may inform care and treatment, and enable the review of outcomes of the care and treatment provided (82). There is an increasing policy emphasis on the use of PROMs in health and social care to ensure that the outcomes of care are patient-centred, and commissioning is increasingly being based on care outcomes rather than care processes (83). As a consequence, there is a growing use of PROMs in palliative care to support assessment and evaluation of physical, emotional, social and existential concerns important to the patient (7, 84), and to demonstrate effective care and improved outcomes for patients with complex needs and their family members (85).

PROMs have been used successfully with people with dementia to measure, for example, quality of life (86). However, it becomes increasingly challenging for people with advancing dementia and difficulty expressing their wishes or concerns to complete a PROM; and proxy-reported measures may be used instead (86). Proxy-reported measures may also measure patient-centred concerns, but are completed by a person who knows the patient well, often a family member or a professional providing care (87). However, there are threats to the validity of using proxy-reported measures in people unable to express their wishes or concerns; with regards to the degree to which the proxy account reflects the concerns of the person. This is particularly the case for subjective symptoms or concerns such as pain and depression (88). Proxy assessment may be conducted through clinical examination, or through observation of behaviour or signs, a method which many of the pain assessments developed for this population utilise (89). Good knowledge of the person and regular close contact with the person may enhance assessment by providing the opportunity for close observation and detection of any changes to presentation and behaviours (78). Used as part of routine care, PROMs and proxy-reported outcome measures,

together known as patient-centred outcome measures (PCOMs) are means of assessing and monitoring symptoms and concerns important to the patient in order to improve patient-centred care and patient-centred outcomes, and are therefore complex interventions (7). This is due to the interacting components involved e.g. assessment, communication, change of care delivery; the requirements for behaviour change and flexible delivery; and potential for multiple outcomes (2).

1.3.2 Theory of change

This study uses a theory of change to inform the intervention development. The study commenced with developing a theoretical model to inform how a PCOM used in routine care may change care processes to improve outcomes for people with dementia living in residential care homes. Using the theory of change informed the theoretical model underpinning the study to provide a theoretical understanding of how the complex intervention of a PCOM may work. The theoretical model also underpinned the study design and methods including the use of mixed methods, methods of data collection and data analysis, and implementation requirements for using a PCOM in routine care.

Theory of change is a 'theory of how and why an initiative works' (90). It presents a hypothetical causal pathway in which each step can be tested. The theory is presented in diagrammatic format to demonstrate the expected causal mechanisms of action in which an intervention is expected to achieve its intended outcomes (91). It provides a pragmatic and flexible framework in unpacking the 'black box' of a complex intervention, and allows for multiple pathways without a pre-defining structure (91) and may be developed from research evidence or constructed by stakeholders (92). Theory of change has been proposed as a means of strengthening the application of the Medical Research Council guidance for developing and evaluating complex interventions (MRC guidance) (2, 93) throughout all the phases (91, 94). For example, and in this study, theory of change in the development of a complex intervention supports stakeholder engagement, makes explicit the likely mechanisms of action, and helps adapt and tailor the intervention to the context (91, 94). While, in feasibility testing, it helps identify any implementation barriers and applicability, and acceptability of the intervention (91, 94). A criticism of theory of change is that it remains relatively superficial and does not provide the in-depth understanding of how an intervention may work

within the context (95) while its strength is that it provides a theoretical means of managing complexity, and multiple components of an intervention (95).

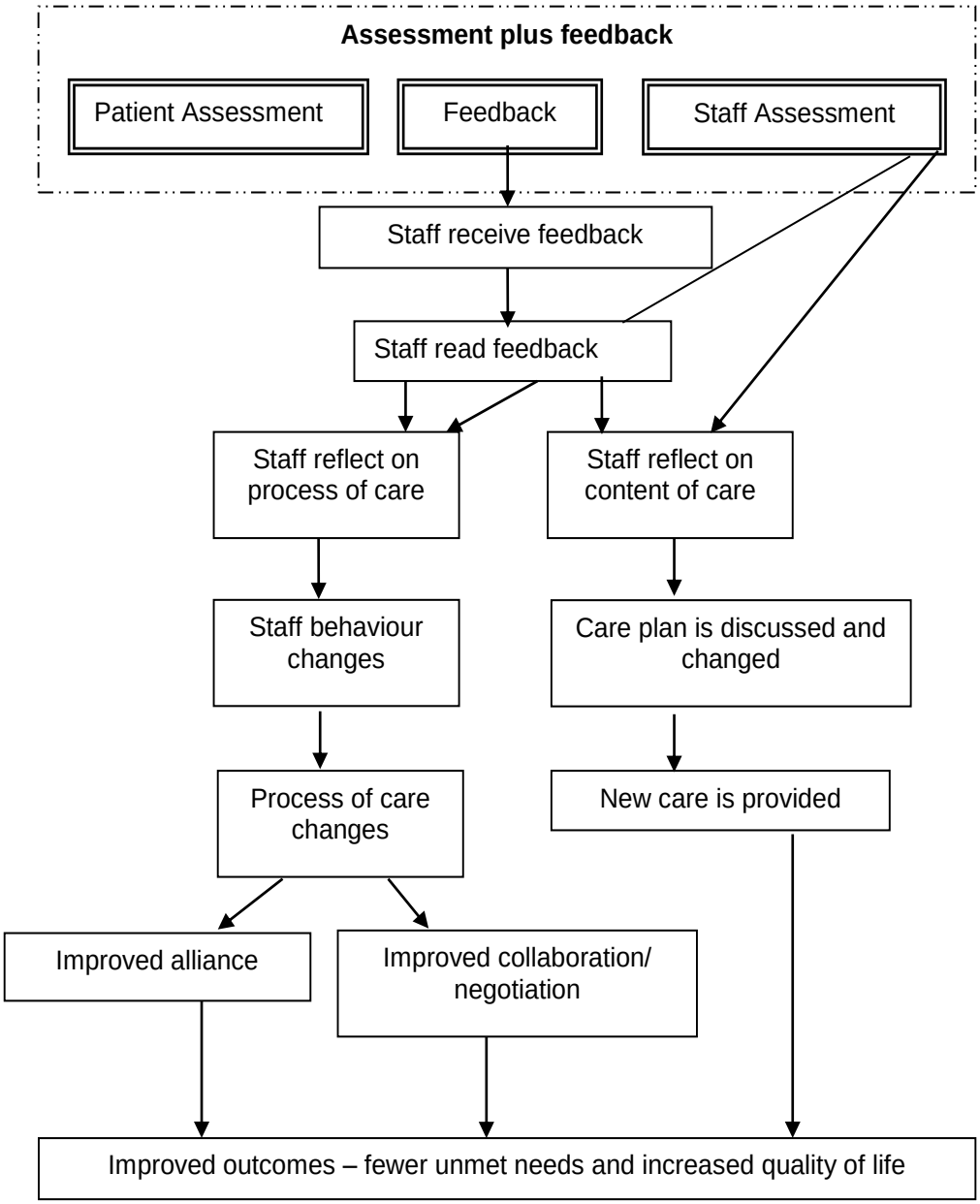
1.3.3 Patient-centred outcome measures used in routine care of people with dementia in care homes: theoretical underpinning of a complex intervention

Few studies have tested the effectiveness of using PCOMs in routine care for people with dementia, and specifically for those living in care homes (7). Those that have been conducted have predominantly utilised pain assessment to examine whether this improved detection and management of pain (96) rather than comprehensive assessment of all physical, emotional, social and existential concerns that people with dementia may experience. However, there is some qualitative evidence that the use of a palliative care symptom assessment tool may support care processes and improve quality of care of people with dementia in care homes (97). In this study, the Minimal Documentation system for Palliative care (MIDOS) tool was used in the care of people with advanced dementia in care homes to assess physical and psychological symptoms. Care home staff perceived using this PCOM as beneficial in supporting comprehensive assessment, and supporting communication within the care home (97).

An underpinning theoretical model is an essential component of a complex intervention to understand the linkages between the problem and the intended outcomes (2). To understand how using a PCOM in routine care may work to change care processes i.e. the mechanisms of action, and improve outcomes (potential benefit) for people with dementia, it is important to have a theoretical model. A theoretical model makes explicit the causal assumptions of the intervention. Understanding the assumptions is essential in understanding the intervention, evaluating uncertainties, and extending the understanding of the intervention including how it is to be delivered and implemented within the context. By making the assumptions explicit, the intervention can be evaluated against the theory and refined accordingly (2, 3, 5, 93). Theory further provides a conceptual organisation to the overall study, including the planning and conduct of the design, methods, and analysis and interpretation of data. In mixed-methods research, an underpinning theory provides a means of structuring, organising, and integrating the data from both qualitative and quantitative methods to understand the phenomena under study (98, 99).

This study therefore draws upon the use of outcome measurement in clinical care to develop a theoretical model of how a PCOM used in routine care may support assessment and management of symptoms and concerns to potentially benefit people with dementia living in residential care homes.

Theoretical models of the likely mechanisms of action of using PCOMs in routine clinical care have been developed. Slade (100) addressed the use of *routine outcome assessment* in clinical care and proposed a testable model of the expected mechanisms of action. This model, developed for mental health services, proposes the use of routine patient- and staff-reported outcome measures, and feedback of the data to both groups. Completing the outcome measure and/or receiving feedback may prompt mental health professionals or patients to reflect on the process or content of care, resulting in changes to process and/or content of care, and improved patient outcomes including reduced unmet need and improved quality of life (100) (Figure 2). However, there are limitations to applying this model to the care of people with dementia in care homes. The role of family members (including friends or others close to the person with dementia) is not taken into consideration in this model. Palliative care aims to intervene to address the concerns of people with a life-limiting or chronic illness and their family members (14, 101). It is important that the model incorporates family members' roles in the care of people with dementia, and also understand how using a PCOM may benefit family members. Another limitation is that the model is developed for the health care setting and therefore does not take into account the requirement for care home staff to access health care on behalf of people with dementia and the challenges associated with this.



*Staff model, the same processes may occur for patients

Figure 2 Mechanisms of action for staff involved in routine outcome assessment and feedback (100)

Greenhalgh and colleagues (102) proposed a theoretical model to demonstrate how PROMs used in routine clinical care may improve patient outcomes. In this model, a series of hypotheses, with the strength of evidence based on trial results are proposed demonstrating the mechanisms of action of using and feeding back information from PROMs to health care professionals. Mechanisms of action include improved communication between health care professionals and patients, detection of unrecognised problems, monitoring of treatment response, and changes to health care professionals and patient behaviour; resulting in improved patient satisfaction and

improved health outcomes (102) (Figure 3). Once again, there are limitations to applying this model to the care of people with dementia in care homes, including the role of family members, and the challenges of integrated working between care home staff and health care professionals. In addition, this model is developed to understand the use of PROMs in routine care. The mechanisms of action of using a care home staff reported PCOM are likely to be different to those of PROMs used in clinical care.

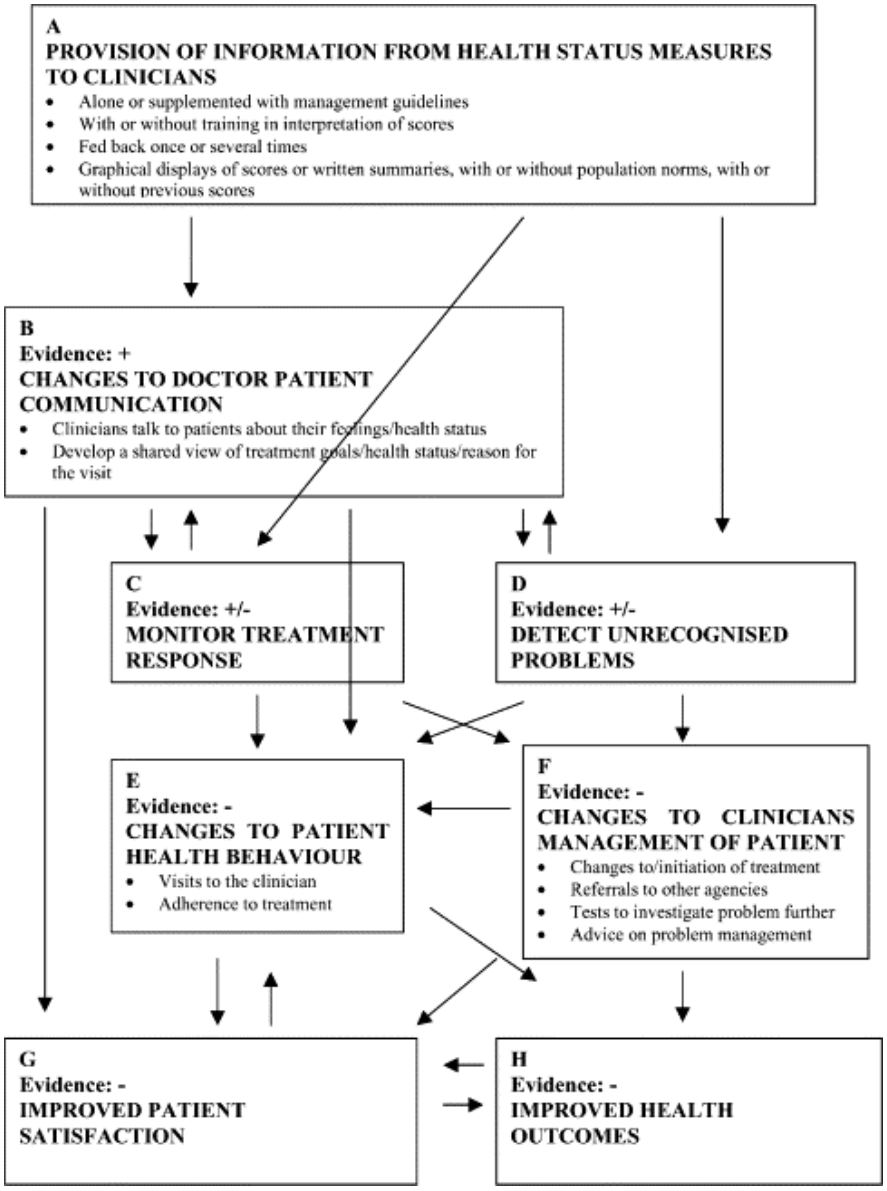


Figure 3 Outcomes and hypotheses in the trials evaluating the impact of health status measures on clinical decision-making (102)

These models are useful to identify the expected mechanisms of action of using a PCOM intervention in routine care, and the anticipated patient outcomes. However, adaptations are required to take into consideration:

(i) The likely mechanisms of action of using a care home staff reported outcome measure instead of a PROM.

(ii) The requirement for family members to be included in the assessment, monitoring and care of people with dementia in care homes, and an understanding of potential benefit to family members.

(iii) The requirement for integrated working between care home staff and health care professionals so that care home staff can access health care on behalf of people with dementia.

Consequently, a decision was made to develop a theoretical model that outlines expected mechanisms of using a measure in routine care of people with dementia living in care homes, drawing upon the two existing models (100, 102) but adapting it for this population and setting. In particular, the model was developed with the following considerations:

(i) Terminology: the term 'patient-centred' reflects a clinical setting. Care homes are people's homes and are not clinical settings. The term 'patient-centred' or PCOM was therefore not used for the purposes of this study. In addition, to reflect the use of the outcome measure as a care intervention, rather than as an instrument to measure outcomes for research purposes, the term 'measure' is used rather than 'outcome measure'. Accordingly, the term 'measure' is used henceforth in this thesis.

(ii) The theoretical model reflects that the measure aims to assess symptoms and concerns in people with dementia who may be unable to express their symptoms and concerns verbally.

(iii) Many agencies may be involved in assessment, decision-making and management including the person with dementia, family members and friends of the person with dementia, care home staff (including support staff, night staff, keyworkers and managers), and health care professionals (50, 62-64, 103). Communication between all agencies is an essential process that needs to be incorporated at all stages.

The theoretical model developed for this study draws upon both models (100, 102) and takes into account these three considerations. Figure 4 overviews the theoretical model underpinning this thesis. The model details the expected mechanisms of action of the use of a measure in routine

care to support assessment, timely delivery of care and treatment, and review and improve outcomes. The key expected mechanisms of action comprise:

(i) **Routine use of the measure** in care home staff's day-to-day care and review of people with dementia. Routine use means that care home staff are prompted at regular points in a person's care to assess and monitor symptoms and concerns. This includes gaining an account from the person with dementia either verbally or through observation when providing care, speaking to family members and colleagues, and reading case notes.

(ii) Completing the measure supports care home staff to **detect symptoms and concerns** in people with dementia. Scores on the measure may help care home staff prioritise treatment of symptoms and concerns.

(iii) If required, the completed measure facilitates **integrated working** by supporting care home staff to communicate symptoms and concerns to health care professionals. The completed measure provides a documented summary of the symptoms and concerns experienced by the person. This provides a means of communicating information to health care professionals in an easily accessible format. In addition, scores on the measure support communication of severity and urgency of symptoms and concerns to support health care professionals in prioritising treatment.

(iv) The process of using the measure, detecting symptoms and concerns and communicating assessments to health care professionals prompts **shared decision-making and care planning** between family members, care home staff, and/or health care professionals. Where possible, people with dementia too may be enabled to participate in shared decision-making in care planning, particularly when they are able to express their wishes and concerns. A comprehensive assessment that can be easily shared between all agencies supports communication and prioritisation of care needs, thus supporting shared decision-making and care planning.

(v) Shared decision-making and care planning may result in **changes to care provided** by care home staff. Care home staff may identify symptoms and concerns that they are able to address through changes in the care provision. This may be, for example, tailoring activities to enable and support the person to engage in activities.

(vi) Shared decision-making and care planning may result in **changes to health care management** by health care professionals. This improves treatment of symptoms.

(vii) **Referrals to other services** including secondary or specialist services such as mental health teams, specialist palliative care, or therapy services results from shared decision-making and care planning.

(viii) As a consequence of shared decision-making and care planning, **people with dementia and family members change behaviour.** People with dementia may feel that their symptoms and concerns are being better addressed, and have increased satisfaction or engagement with care. A reduction in behaviour that challenges, resulting from psychological distress, may also occur if distressing symptoms and concerns are adequately addressed. Behaviour that challenges resulting from physiological causes may also be addressed, through improved treatment and management from care home staff, family members and health care professionals. Family members too may feel better able to engage in the care, and therefore may take an active role in the care of people with dementia.

(ix) Changes to care provision, to health care management and behaviour of people with dementia and family members; and referrals to other services result in **improved outcomes for people with dementia and family**. This includes reduced unmet need, improved quality of life and improved satisfaction with care.

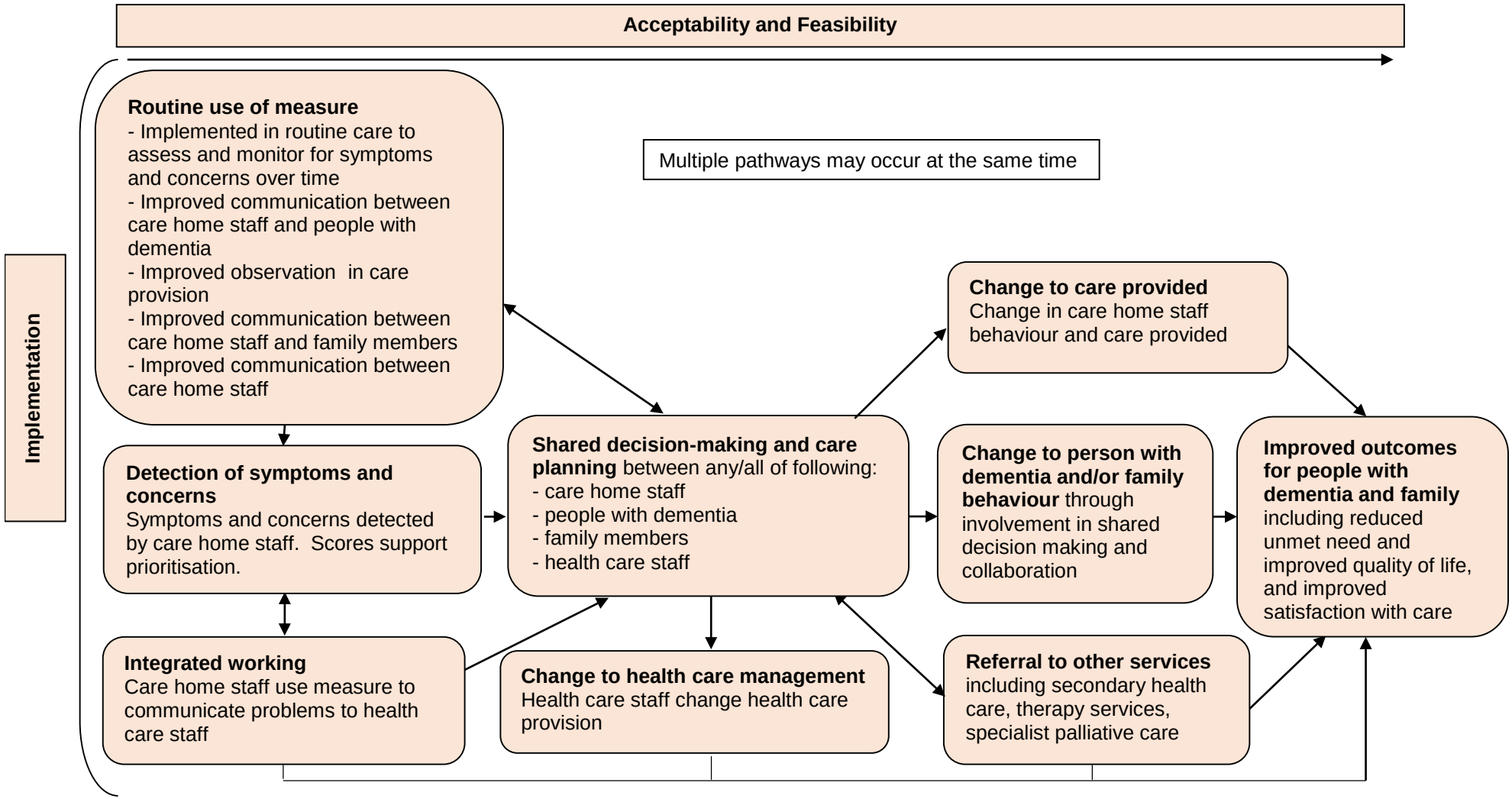


Figure 4 Theoretical model of expected mechanisms of action of measure used in routine care of people with dementia in care homes

1.3.4 Measurement properties for use in routine care in care homes

Also included in the theoretical model are the particular requirements of measures used in routine care to support its use and changes to care processes; as well as the consideration of implementation into routine care.

Outcome measures developed for use in research may have less utility when used in routine care, with barriers to their use. Some of these barriers are related to resources, but many are related to the properties of the measure. Table 1 identifies measure-related barriers to using measures in routine clinical care (11, 12), and requirements of measures identified in palliative care and mental health literature to overcome these barriers (11-13). These requirements are categorised in Table 1 according to the following commonly accepted definitions from the literature on clinical measurement (9-13), although the same requirements are important in non-clinical care home settings (104).

Validity: the degree to which an instrument measures what it purports to measure (9).

Reliability: 'the degree to which the measurement is free from measurement error' (9).

Responsiveness: the ability of a measure to detect change over time in the construct to be measured (9).

Interpretability: the degree to which one can assign qualitative meaning, or clinical connotations, to a measure's score(s) or change in score(s) (9).

Acceptability: whether patients (for patient-reported measures) or staff/health care professionals are prepared to and willing to use the measure (10), and its suitability for intended use in clinical care (11).

Comprehension: how patients or staff/health care professionals understand, interpret terms, and choose their responses (10).

Feasibility: whether patients or staff/health care professionals are able to use the measure in their respective setting or context (10).

Availability: the requirement for measures, and additional training and resources, to be easily and freely accessible (12, 13).

Table 1 Barriers, measurement requirements and properties of measures used in routine clinical care

Measure-related barriers (i.e. not staff-related or resource-related)	**Requirements of measure to minimise barriers**	**Measurement property**
Lack of validated version for setting and/or population (12)	Valid and reliable for population and setting (11)	**Validity and reliability**
The measure is not able to detect changes when the construct being measured has changed (10) resulting in limitations in monitoring symptoms and concerns, and changes in symptoms and concerns over time	Responsive to change: the measure detects clinically meaningful changes (11)	**Responsiveness**
Interpreting what the score means clinically may be challenging. This is particularly the case for multi-item measures where the result is not immediately obvious (10)	The results of the measure can be interpreted clinically and are relevant (11). Staff are able to make decisions about care based on the scores (105)	**Interpretability**
Lack of available training or guidance on how to use the measure and interpret the scores (12) Require trained researchers to administer (11)	Measures are easy to use, simple, and easy to score (11, 13) Simple instructions, do not require formal training (13)	**Acceptability and comprehension**: easy to use and score, any training is easy to understand and simple
Not clinically relevant to the population (11)	Relevant and suitable for its intended use in clinical practice or care (11) Relevant to the intended population with familiar language and concepts, avoiding jargon, with relevant choice of language (13)	**Acceptability and comprehension**: relevant to population and to clinical purposes, language is relevant and easy to comprehend
The costs of using the measure outweigh the perceived benefits, and the information obtained from completing the measure (13)	Value to care: the benefits to use outweigh the relative costs (13)	**Acceptability**: providing value to care
Burdensome for staff (12) Too lengthy for clinical care (11)	Brief, quick to complete (11, 13)	**Feasibility**: brief and quick to complete
Not able to access information on measure (12) Limited access to measure (12) Costs for using measure (12) Measure not available in language (12) Lack of training on how to analyse measure data (12)	Access to measure information and training (12) Free and easily available (13)	**Availability**: Measure, training and resources are freely available to health care professionals, translated versions available for international use

1.3.5 Implementation requirements

As with all complex interventions, it is important to consider the process of implementing in practice (3). Implementation is defined as the process through which an intervention is delivered and what is actually delivered in practice (5). This study is not an implementation study and it is beyond its scope to examine the implementation of measures into routine care. Nonetheless, in developing any intervention, it is important to consider implementation from the outset (2). Implementation requirements of the intervention, in this case a measure used in routine care, include important features of the intervention that maximise its implementation such as training and additional resources, and the mechanisms which may support implementation.

1.4 Summary of key points

Changing demographics mean that there is growing number of people living with and dying from dementia. Due to dementia, multi-morbidities, and polypharmacy, people with dementia may have multiple symptoms and concerns. In addition, they may have increasing difficulty expressing their wishes and concerns resulting in challenges to assessment. Undetected and therefore untreated symptoms and concerns may lead to avoidable distress, reduced quality of life and wellbeing, and behavioural complications.

Many people with dementia may move into care homes due to the requirement for increased support and complex care needs. Residential care home staff, the majority of whom do not have a clinical qualification, need to be able to detect and manage symptoms and concerns in people with dementia, and access health care when required. This is despite the challenges of assessing symptoms and concerns in people with dementia, and challenges to integrated working with health care. Family members (including friends and others to close to the person) frequently wish to retain their caring role but often feel excluded from the care of people with dementia resulting in feelings of loss and frustrations, and difficulty adapting to the transition. There are few evidence-based interventions to support assessment and management of symptoms and concerns of people with dementia in care homes, and their family members.

Measures used in routine clinical care may support comprehensive assessment of symptoms and concerns, and change care processes resulting in patient benefit. However, there are gaps in

knowledge of how they may work to improve assessment and management of symptoms and concerns of people with dementia living in care homes; and how they may be best implemented into routine care. It is also important that the measurement properties of such measures are maximised for a non-clinical environment and for residential care home staff without a clinical qualification to use in routine care, in particular, the validity, reliability, responsiveness, interpretability, acceptability, comprehension, and feasibility; and availability to care homes with limited financial resources.

2. Existing measures for people with dementia in care homes [PUBLICATION 1]

This chapter presents a systematic review published in 2016. The systematic review aimed to identify measures to assess symptoms and concerns experienced by people with dementia in care homes. In particular, the review identified measures that care home staff without a clinical qualification are able to use to assess people who have difficulty or are unable to verbally express their wishes and concerns due to dementia. They are therefore measures that do not rely on a clinical examination, rather they use observation of signs and behaviours.

The systematic review identifies the measures and evaluates them according to measurement properties (106), and their applicability for use by care home staff in routine care of people with dementia.

Ellis-Smith *et al. BMC Medicine* (2016) 14:38
DOI 10.1186/s12916-016-0582-x

BMC Medicine

RESEARCH ARTICLE Open Access

Measures to assess commonly experienced symptoms for people with dementia in long-term care settings: a systematic review

Clare Ellis-Smith*, Catherine J. Evans, Anna E. Bone, Lesley A. Henson, Mendwas Dzingina, Pauline M. Kane, Irene J. Higginson, Barbara A. Daveson and on behalf of BuildCARE

Abstract

Background: High symptom burden is common in long-term care residents with dementia and results in distress and behavioral challenges if undetected. Physicians may have limited time to regularly examine all residents, particularly those unable to self-report, and may rely on reports from caregivers who are frequently in a good position to detect symptoms quickly. We aimed to identify proxy-completed assessment measures of symptoms experienced by people with dementia, and critically appraise the psychometric properties and applicability for use in long-term care settings by caregivers.

Methods: We searched Medline, EMBASE, PsycINFO, CINAHL and ASSIA from inception to 23 June 2015, supplemented by citation and reference searches. The search strategy used a combination of terms: dementia OR long-term care AND assessment AND symptoms (e.g. pain). Studies were included if they evaluated psychometric properties of proxy-completed symptom assessment measures for people with dementia in any setting or those of mixed cognitive abilities residing in long-term care settings. Measures were included if they did not require clinical training, and used proxy-observed behaviors to support assessment in verbally compromised people with dementia. Data were extracted on study setting and sample, measurement properties and psychometric properties. Measures were independently evaluated by two investigators using quality criteria for measurement properties, and evaluated for clinical applicability in long-term settings.

Results: Of the 19,942 studies identified, 40 studies evaluating 32 measures assessing pain (n = 12), oral health (n = 2), multiple neuropsychiatric symptoms (n = 2), depression (n = 8), anxiety (n = 2), psychological wellbeing (n = 4), and discomfort (n = 2) were included. The majority of studies (31/40) were conducted in long-term care settings although none of the neuropsychiatric or anxiety measures were validated in this setting. The pain assessments, PAINAD and PACSLAC had the strongest psychometric evidence. The oral health, discomfort, and three psychological wellbeing measures were validated in this setting but require further psychometric evaluation. Depression measures were poor at detecting depression in this population. All measures require further investigation into agreement, responsiveness and interpretability.

Conclusions: Measures for pain are best developed for this population and setting. All other measures require further validation. A multi-symptom measure to support comprehensive assessment and monitoring in this population is required.

Keywords: Dementia, Long-term care, Palliative care, Review, Symptom assessment

* Correspondence: alexandra.c.ellis-smith@kcl.ac.uk
King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, Bessemer Road, London SE5 9PJ, UK

Background

People with dementia in long-term care settings commonly have high levels of comorbidity and symptom burden [1]. Multiple symptoms at all stages of the disease with varying prevalence are reported [1–9], notably pain (12–76 %) [2], dyspnea (8–80 %) [2], depression (9–32 %) [5, 7], anxiety (3–22 %) [5, 7], hallucinations (2–11 %) [5, 7], and delusions (18 %) [5]. Assessment is challenging, with declining verbal communication and cognition and absence of biological markers; with reliance on clinical examination. Untreated symptoms lead to distress and behavioral complications and compromises quality of life, resulting in challenges to clinical management [10] and staff burden [11].

Caregivers providing personal care are well placed to detect and monitor symptoms through daily contact and knowledge of residents [12], and refer to physicians for clinical examination and treatment. Routine use of measures in care supports systematic assessment and monitoring of symptoms, with increased access to treatment and improved outcomes [13]. However, there is limited evidence on their use in long-term care settings [13]. Requirements for such measures are that they are valid and reliable to ensure accurate assessment, responsive to change, clinically interpretable, brief and simple to use [14], and require minimal training [15]. Additionally, measures used by caregivers should not require a clinical qualification or expertise, and should support assessment through proxy-observed behaviors and signs for those residents unable to reliably self-report.

Caregiver assessment in long-term care settings is not well-established for all common symptoms, e.g. psychotic symptoms [16]. However, measures based on caregiver knowledge of the person with dementia without the requirement of clinical expertise, and validated in other settings, may have clinical applicability in long-term care settings and be transferable. With further validation, psychometrically robust and established assessment measures could support caregiver assessment of residents in long-term care.

This systematic review aimed to identify proxy-completed assessment measures of common symptoms experienced by people with dementia, and critically appraise the psychometric properties and applicability for use in long-term care settings by caregivers.

Methods

This systematic review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Additional file 1: PRISMA checklist) [17].

Search strategy

We searched Medline, EMBASE, PsycINFO, CINAHL and ASSIA from inception to 9 April 2014 and updated on 23 June 2015. A search strategy was developed, informed by search strategies used in previous reviews, and a scoping review of common symptoms in people with dementia performed by the authors. A combination of MeSH and keyword terms were used: dementia [18] OR long-term care AND assessment AND symptoms [19] (e.g. pain, dyspnea, depression, dental pain; Additional file 2). The search was supplemented by reference and citation search of included articles using Scopus.

Eligibility criteria

The population comprised people with dementia, or dementia subgroup analyzed separately, in any care setting, e.g. long-term care, inpatient hospital. All settings were included to identify validated measures with potential applicability to long-term care settings. To include measures with high applicability in long-term care, studies with mixed cognitively intact and cognitively impaired participants in these settings were included. Measures were included if they assessed symptoms using proxy-observed behaviors or signs in people whose verbal communication was compromised due to dementia, were validated in English, and were for use in routine care without the requirement of formal clinical training. Caregiver self-administered measures were included as they do not rely on clinicians or trained personnel to administer them, which reduces their applicability for use in care. We excluded studies of:

- Measures that required verbal responses from people with dementia
- Measures that were face-to-face or interview administered to proxies due to limited clinical applicability in routine care
- Behavioral measures that did not identify underlying causes of behavioral change, for example, measures of aggression and sleep disturbance
- Measures not primarily assessing symptoms, including those of frailty, cognition, functioning, disease progression, quality of life, and risk, and process measures, e.g. quality of communication
- Measures that required extensive training that may not be easily accessible or available to caregivers

Studies were identified for inclusion if they were in the English language and evaluated at least two psychometric properties (including one aspect of reliability and validity) of the full measure. Qualitative, review studies, theses, and conference abstracts were excluded.

Study selection

One investigator (CES) reviewed titles and abstracts and excluded all those clearly irrelevant. Full text review was then conducted by one investigator (CES) to exclude

those studies not meeting the inclusion criteria. Studies not clearly excluded were reviewed by a second reviewer (AEB) and the final inclusion of studies was agreed by discussion and consensus. Where further information was required to determine eligibility criteria, the authors were contacted. When authors were not contactable, a decision was made based on available information.

Data extraction and assessment of quality criteria of measures

One reviewer (CES) extracted all data from each study into a standardized data extraction Excel template, and assessed the psychometric properties using quality criteria for measurement properties of health status questionnaires. Data extraction included (1) study setting, sample, and who the measure was administered by; (2) measurement properties, including method of administration, number of items, rating period, time to administer, and training required; and (3) psychometric properties, including content validity, internal consistency, criterion validity, construct validity, reproducibility (agreement and reliability), responsiveness, floor and ceiling effects, and interpretability [20]. Where applicable, psychometric properties were extracted on dementia subsamples. Evaluation of each psychometric property was based on detailed and well-established quality criteria [20], with four ratings: positive (strong psychometric properties using adequate design and method), intermediate (some but not all aspects of property is positive, or there is doubt about design and method used) [21], negative (psychometric property does not meet criteria despite adequate design and method), or no information. Details of methodological and quality criteria are detailed in Terwee et al. [20] but include, for example, requirement for formulated hypotheses with 75 % of hypotheses supported by findings for construct validity, intraclass correlation coefficient (ICC) or Cohen's kappa ≥0.70 for reliability, ≤15 % obtaining highest or lowest possible scores for floor and ceiling effects, and sufficient sample size ≥50 for all (sub)groups. As quality rating of sensitivity and specificity are not included in the Terwee et al. [20] quality criteria, we calculated the sum of percentages misclassified, i.e. false positives and false negatives, as follows: [(1 − sensitivity) + (1 − specificity)] [22] and gave a positive rating for criterion validity of misclassification less than 50 %, i.e. better than chance [23]. A second reviewer (LAH, MD, or PMK) checked the data extraction and independently assessed the quality. The first and second reviewer resolved any disagreements by consensus. Where authors did not state which aspect of validity or reliability were being evaluated, the investigators made a judgement based on the methods used.

Results

Study selection

A total of 28,386 studies were identified through database searches. After deduplication, 19,942 titles and abstracts were screened, of which 1,302 were retained for full-text review. Following an independent review of 154 studies, 36 were retained for inclusion. Reasons for exclusion were required verbal responses from person with dementia (n = 125), face-to-face or interview administered to proxy (n = 38), no symptom assessment (n = 289), not dementia population (n = 64), not validated in English (n = 169), not or insufficient psychometric evaluation (n = 374), dissertation/conference abstract/study not published in English/other (n = 195), and administration required extensive training (n = 12). Following citation and reference searches, an additional four studies were identified for inclusion, resulting in a total of 40 studies (Fig. 1).

In total, 32 measures were identified, assessing pain (n = 12), oral health signs and symptoms (n = 2), multiple neuropsychiatric symptoms (n = 2), depression (n = 8), anxiety (n = 2), psychological wellbeing (n = 4), and discomfort (n = 2). The majority of studies were conducted in long-term care settings (n = 31), with seven studies recruiting from outpatient clinics [24–30]. One study was conducted in an orthopedic ward [31] and one in psychogeriatric wards [32]. Only 11 out of the 40 studies included measures administered by non-clinically trained caregivers: six pain measures [33–39], two oral health signs and symptoms measures [40, 41], two depression measures [42, 43], and one psychological wellbeing measure [44]. The neuropsychiatric symptoms [26, 30] and anxiety [24] measures were all validated with unpaid caregiver proxies in community settings. Additional file 3 provides setting and population details of each study.

Quality assessment agreement between reviewers was 86 %. Disagreements were resolved by consensus, e.g. data checking, and discussion regarding adequacy of hypotheses and whether findings supported hypotheses.

The strength of the psychometric properties of measures validated in long-term care settings

Of those measures validated in long-term care settings, the measures with strongest psychometric properties for pain were Pain Assessment in Advanced Dementia (PAINAD) [31, 45–48], and Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC/PACSLAC-II) [35, 36, 45, 47, 49, 50]. The Oral Health Assessment Tool (OHAT) [40] and Discomfort Scale-Dementia Alzheimer's Type (DS-DAT) [47, 51] had the strongest psychometric properties for oral health and discomfort, respectively (Table 1). The depression measures demonstrated weak abilities to accurately

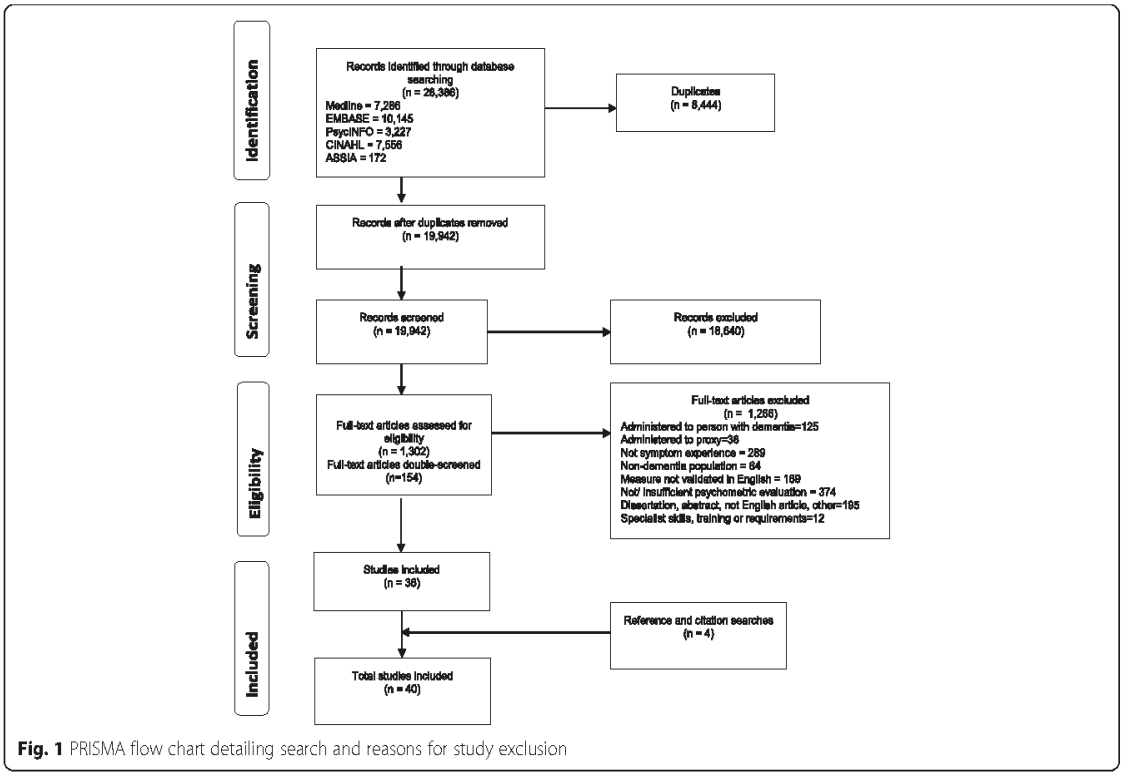


Fig. 1 PRISMA flow chart detailing search and reasons for study exclusion

detect depression in this population, and all the psychological wellbeing measures require further validation. No measures achieved positive ratings for all psychometric properties with information lacking on agreement, floor and ceiling effects, responsiveness, and interpretability (Additional file 4).

Measures were administered through observation during provision of routine care, observations during specified activities or time periods, examinations, knowledge of resident, all available information available to caregiver, or video recordings of residents. Rating periods ranged from one minute to one month, with time taken to complete ranging from 30 seconds to 10 minutes. Measurement training ranged from none to 4 hours (where details were provided), and up to 2 days for validation purposes. Table 2 summarizes the elements of the measure (scoring, rating period), and the feasibility (measure length, time to complete, training requirements) and applicability (method of administration used in the included studies, type of training) of measures; Additional file 5 provides details of all measures.

Pain

The measures identified to assess pain were the Abbey Pain Scale (APS) [33, 47, 52], Checklist of Nonverbal Pain Indicators (CNPI) [45, 46, 52, 53], CNA Pain Assessment Tool [34], Doloplus-2 [52], Mahoney Pain Scale [38], Non-communicative Patient's Pain Assessment Instrument (NOPPAIN) [45, 54], PAINAD [31, 45–48], PACSLAC [36, 45, 47, 49, 50] and PACSLAC-II [35], Pain Assessment in Communicatively Impaired [37, 50, 55], Pain Assessment for Dementing Elderly (PADE) [39, 45], and Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders [29].

Of these, the PAINAD and PACSLAC have been the most extensively evaluated with the strongest psychometric properties. PAINAD has good internal consistency (Cronbach's alpha of 0.70 and greater) [46, 47]. Inter-rater reliability is strong (kappa = 0.87 [45], ICC ≥0.87 [47]) in two studies, although one study reported an ICC of 0.24 when administered in rest situations and 0.80 during movement situations [46]. PAINAD has demonstrated good construct validity against APS, PACSLAC, CNPI, NOPPAIN, and PADE at rest and during exercise ($r \leq 0.62$) [45, 47]. The PACSLAC demonstrated good construct validity against the NOPPAIN, CNPI, PADE, APS, and PAINAD at rest and during exercise ($r \leq 0.56$) [45, 47]. Inter-rater reliability at rest and movement situations is consistently high (ICC ≥0.76) [45, 47, 50]. Both measures require

Table 1 Evaluation of quality criteria of measures with strongest psychometric properties validated in long-term care settings

Name of measure	Content validity	Internal consistency	Criterion validity	Construct validity	Reproducibility		Responsiveness	Floor and ceiling effects	Interpretability
					Agreement	Reliability			
Pain									
PAINAD [48]	+	?	0	?	0	?	0	–	?
PAINAD [46]	?	?	0	?	0	–	0	–	0
PAINAD [47]	0	+	–	+	0	+	0	0	?
PAINAD [45]	0	?	?	+	0	+	0	0	0
PACSLAC [49]	+	?	0	?	0	0	0	0	0
PACSLAC [36]	0	0	?	?	0	?	0	0	0
PACSLAC [47]	0	?	–	+	0	+	0	0	?
PACSLAC [45]	0	?	?	+	0	+	0	0	0
PACSLAC [50]	0	0	–	?	0	+	0	0	0
PACSLAC-II [35]	+	?	0	+	0	–	0	0	0
Oral health									
OHAT [40]	+	0	?	0	0	+	?	–	0
Discomfort									
DS-DAT [51]	+	?	0	?	0	?	0	0	0
DS-DAT [47]	–	–	–	+	0	+	0	0	?

PAINAD, Pain Assessment in Advanced Dementia; PACSLAC, Pain Assessment Checklist for Seniors with Limited Ability to Communicate; OHAT, Oral Health Assessment Tool; DS-DAT, Discomfort Scale for patients with Dementia of Alzheimer's Type
+ A positive rating indicates strong psychometric properties according to quality criteria using adequate design and method [20]
? Intermediate [21] rating indicates some but not all aspects of psychometric properties are positive, or there is doubt about the design and method used [20]
– A negative rating indicates psychometric properties do not meet criteria despite adequate design and method used [20]
0 No information provided in the paper [14]

further validation when used by caregivers as these have predominantly been evaluated when administered by trained research assistants or clinicians. PACSLAC-II is a modified and shortened version of the PACSLAC based on theoretical and evidence developments in pain assessment, and has good content validity [35]. Only one study evaluating the psychometric properties of PACSLAC-II [35] was identified, and was conducted in long-term care settings and administered by trained research assistants and caregivers. Evidence for construct validity was supported with expected strong correlations with PACSLAC, CNPI, PADE, and PAINAD in pain and non-pain conditions ($r \geq 0.56$), and expected weak correlations with the Cornell Scale for Depression in Dementia (CSDD) (non-pain condition: $r = -0.05$, vaccination: $r = 0.10$, movement: $r = -0.06$). PACSLAC-II demonstrated ability to discriminate between non-pain and painful conditions ($P < 0.01$). Internal consistency was strong (Cronbach's alpha ≥0.74) and interrater reliability kappa was 0.63.

The NOPPAIN [45, 54] and CNA Pain Assessment Tool [34] are the only measures of pain developed for administration by non-clinically trained caregivers. The NOPPAIN is completed by observations carried out during routine care tasks, and is designed for easy administration with limited training [54]. NOPPAIN has high correlation ($r \leq 0.70$) against CNPI, PACSLAC, PADE, and PAINAD with an inter-rater reliability kappa of 0.73 when administered by trained research assistants [45].

Oral health signs and symptoms

Two measures, the Brief Oral Health Status Examination (BOHSE) [41] and the OHAT [40], were identified. Both assess oral health in long-term care residents and are administered by caregivers through oral examination of the resident. OHAT was derived from BOHSE and is simpler. OHAT comprises eight items and involves 3 hours of training to caregivers with calibration. When compared against comprehensive examination by a dentist, the Pearson correlation coefficients for each item ranged from −0.1 to 1.0 (n = 21). Test-retest reliability item-level unweighted kappa ranged from 0.51 to 0.71, with a total score ICC of 0.78. Inter-rater reliability item-level unweighted kappa ranged from 0.47 to 0.66 with a total score ICC of 0.74 (n = 485). Further testing in a larger sample is required to test validity.

Multiple neuropsychiatric symptoms

The Neuropsychiatric Inventory Questionnaire (NPI-Q) [26] is an unpaid (usually family) caregiver self-administered version of the well-validated and extensively-used NPI [56]. The NPI is sometimes reported as a behavioral measure, but was included in this review as it

Table 2 Summary of measure details, methods of administration, and feasibility and applicability in care

	Measures	Number of items (range)	Scoring (ranges)	Methods of administration	Rating period	Time to compete (range)	Training required
Pain	APS	5–60	0–5 to 0–60	Observation over specified time period	1 minute specified observation time, observation during specified activities, observations during all personal care provision	30 seconds to 5–10 minutes	Most measures do not require any formal training Two have been specifically developed for non-clinically trained care staff
	CNPI			Observation during specified activity			
	CPAT			Observation during routine care			Training for raters in the studies ranged from 5 minute training video to 2 hours, or continued training throughout data collection period
	Doloplus-2			From memory based on knowledge of resident			
	MPS						
	NOPPAIN			Ratings of video recordings of activities or pain events			
	PAINAD			Signs of pain including facial, behavioral, vocal, functional			
	PACSLAC(-II)						
	PACI						
	PADE						
	PBOICIE						
Oral health	BOHSE	8–10	0–16 to 0–20	Observation and examination	Examination period	6–8 minutes	3–4 hours of training, with calibration
	OHAT						
Neuropsychiatric	NPI-Q	12–81	0–36	Observation and knowledge of person	Last 4 weeks	5 minutes	None
	CDBQ		0–248				
Depression	BDI-modified	7–21	0–15 to 0–80	Observation, all available information sources, knowledge of person	Last week to last 4 weeks	No information	No training, 30 minutes training or provision of instructions and instruction manual
	CESD-modified						MDS coordinator usually registered nurse
	CSDD-modified/ CSDD-M-LTCS						
	DDMS						
	DSS						
	CS-GDS						
	Hayes and Lohse Non-verbal Depression Scale						
	MDSDRS						
Anxiety	GAI-modified	8–20	0–20 to 8–40	Modified to be self-administered by informal caregiver, based on knowledge of person	Last week	No information	None
	PSWQ-A-modified						
Psychological wellbeing	PGCARS	5–11	0–90	Observation	5 minutes to last 24 hours	5–10 minutes	Group and one-to-one teaching sessions with supervised practice
	PWB-CIP						
	AARS						
	AER						

Table 2 Summary of measure details, methods of administration, and feasibility and applicability in care *(Continued)*

				Ratings of video recordings			Training for raters in the studies ranged from none to 2 days
Discomfort	DBS DS-DAT	9–17	0–17 to 0–102	Rated based on information from informants, observations and resident interactions	Past week	No information	MDS coordinator, usually registered nurse
				Observation over specified period and activity program	5 minute observation or specified activity program		DS-DAT requires training and may have limited clinical applicability as complex to learn
							Training for raters included continued training throughout data collection period

APS, Abbey Pain Scale; CNPI, Checklist of Nonverbal Behaviors; CPAT, CNA Pain Assessment Tool; MPS, Mahoney Pain Assessment Tool; NOPPAIN, Non-communicative Patient's Pain Assessment Instrument; PAINAD, Pain Assessment in Advanced Dementia; PACSLAC, Pain Assessment Checklist for Seniors with Limited Ability to Communicate; PACI, Pain Assessment in Communicatively Impaired; PADE, Pain Assessment for Dementing Elderly; PBOICIE, Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders; BOHSE, Brief Oral Health Status Examination; OHAT, Oral Health Assessment Tool; NPI-Q, Neuropsychiatric Inventory Questionnaire; CDBQ, California Dementia Behavior Questionnaire; BDI-modified, Beck Depression Inventory – modified; CESD-Modified, Center for Epidemiologic Studies Depression Scale – modified; CSDD-modified, Cornell Scale for Depression in Dementia - modified; CSDD-M-LTCS, Cornell Scale for Depression in Dementia Modified for use by Long Term Care Staff; DDMS-modified, Depression in Dementia Mood Scale – modified; DSS-modified, Depression Signs Scale – modified; GDS, Geriatric Depression Scale; MDSDRS, Minimum Data Set Depression Rating Scale; GAI-modified, Geriatric Anxiety Inventory – modified; PSWQ-A-modified, Penn State Worry Questionnaire – Abbreviated – modified; PGCARS, Philadelphia Geriatric Center Affect Rating Scale; PWB-CIP, Psychological Wellbeing in Cognitively Impaired Persons; AARS, Apparent Affect Rating Scale; AER, Apparent Emotion Rating Instrument; DBS, Discomfort Behavior Scale; DS-DAT, Discomfort Scale for patients with Dementia of Alzheimer's Type; MDS, Minimum Data Set

assesses symptom experience, including depression, anxiety, hallucinations and delusions, and provides observational signs to support assessment of these symptoms. The NPI-Q subscales demonstrated high correlations with the original clinician-administered NPI subscales ($r < 0.70$, $n = 60$). The California Dementia Behavior Questionnaire [30] was designed to assess behavior, but was included in this review as the majority of items assess the symptoms of depression and psychosis and is completed based on unpaid caregiver observations. Neither of these measures have been validated in the long-term care setting.

Depression

Of the ten depression measures identified, two were developed for the purpose of assessment of verbally compromised people with dementia: the Minimum Data Set Depression Rating Scale [57–60], and Hayse and Lohse Non-Verbal Depression Scale [61]. The former is a seven-item scale derived from Minimum Data Set 2.0 items and developed to screen for depression by caregiver staff drawing upon observations during routine care; designed for long-term care settings it has high clinical applicability and is the most extensively psychometrically evaluated. However, evidence for detecting depression against gold-standard diagnosis of depression at a score cut-off point ≥3 is mixed with sensitivities and specificities of 0.91/0.69 (40 % misclassified, $n = 82$) [58] and 0.23/0.97 (80 % misclassified, $n = 145$) [57].

The CSDD is designed to be administered through interview with the person with dementia and a proxy but was modified for proxy-completion in two studies [32, 43]. Watson et al. [43] modified the CSDD for use by long-term caregiver staff most involved in the resident's care using all available information to make the assessment (CSDD-M-LTCS). Modifications involved cognitive testing to remove technical language and changing response options from severity to frequency. Sensitivity and specificity against geriatric psychiatrist diagnosis was 0.33/0.86 (81 % misclassified, $n = 112$). Test-retest reliability was strong (≥0.70) but limited by small sample size (ICC = 0.83, $n = 25$) and inter-rater reliability ICC was 0.20 (n=111).

The Depression Signs Scale and Depression in Dementia Mood Scale [32] were originally designed to be administered based on clinical interview with the person with dementia and information from proxies, but were modified to be completed based on all available information to psychogeriatric ward staff.

The Geriatric Depression Scale (GDS) [27, 28, 42], Beck Depression Inventory [27], and Center for Epidemiologic Studies Depression Scale [27] were not originally developed for dementia but have been used in this population, either through clinical interview or self-report. In the included studies, they have been modified for proxy-completion by unpaid caregivers. The evidence for validity and applicability for use in long-term care by caregivers is therefore limited. One study examined caregiver-completed Collateral Source-GDS (CS-GDS) 30 and 15 versions in long-term care compared to gold standard

diagnosis of depression [42]. In the dementia subsample (n = 35), sensitivities and specificities for the CS-GDS-30 and CS-GDS-15 were 0.70/0.56 (74 % misclassified) and 0.71/0.64 (66 % misclassified), respectively. Pearson correlation coefficient between CS-GDS and GDS ranged from 0.50 to 0.61 [42].

Anxiety

Two anxiety measures, the Collateral-completed Geriatric Anxiety Inventory and the Penn-State Worry Questionnaire-Abbreviated were identified in the same study [24]. Both were modified in this study to be proxy-completed by unpaid caregivers. Sensitivity and specificity for the two measures, against gold-standard clinician-administered MINI-International Neuropsychiatric Inventory [62], were 0.62/0.93 (45 % misclassified) and 0.81/0.73 (46 % misclassified), respectively (n = 41). This study was not conducted in long-term care settings and proxies were therefore not caregiver staff. The measures' validity and applicability in this setting were therefore not established.

Psychological wellbeing

We identified four measures focused on psychological wellbeing. These were Psychological Wellbeing in Cognitively Impaired Persons [25], the Philadelphia Geriatric Center Affect Rating Scale (PGCARS) [63], Apparent Affect Rating Scale (AARS) [44], and the Apparent Emotion Rating Instrument (AER) [64]. The AARS and AER are both derived from PGCARS, originally developed by Lawton et al. [65]. However, this study was not included due to extensive training over 1 month provided to research assistant administrators [65].

The PGCARS, AARS, and AER were all validated in nursing home settings, and AARS and AER were administered by caregivers in the validation study. All three measure positive and negative affect, including items of pleasure, interest, anger, anxiety, and depression/sadness. All these measures require further psychometric evaluation.

Discomfort

The term discomfort is operationalized as the presence of a negative emotional/physical state that can be observed [51]. The Discomfort Behavior Scale (DBS) was developed to assess discomfort/pain [66]; it was derived from items on the Minimum Data Set 2.0 and it has therefore been developed for use in long-term care. It is administered based on review of all available information, including direct observation and communication with residents, discussions with family, and review of records [66]. Internal consistency of DBS is positive (Cronbach alpha = 0.77, n = 9,672) [66]. However, only one psychometric evaluation of the DBS was identified and further evaluation is warranted.

The DS-DAT [47, 51] does not require clinical training. Neither of the studies identified reported the requirement for extensive training and DS-DAT was therefore included in this review. DS-DAT has, however, been critiqued as complex to use and requiring significant training [67]. As such, it may not be useful as a symptom assessment tool in routine care provision. It has demonstrated expected high correlations with pain assessment measures PAINAD, APS, and PACSLAC (≥0.63) and a strong inter-rater reliability ICC at rest (0.83) and exercise (0.85, n = 62) [47].

Discussion

Key findings

To our knowledge, this is the first systematic review to identify and appraise assessment measures of symptoms commonly experienced by people with dementia for use in long-term care settings. Our review identified 32 proxy-completed measures of common symptoms experienced by people with dementia. Of these measures, those that assess pain possess the strongest evidence of psychometric properties. Progress on all the other measures is promising, although oral health, psychological wellbeing, and discomfort measures require further psychometric evaluation, and there have been challenges in developing a measure that accurately detects depression. Neither of the two neuropsychiatric or two anxiety measures were validated in the long-term care setting. Furthermore, we found only 11 studies where measures were validated when administered by non-clinically trained caregivers even though these caregivers are frequently in the best position to detect changes quickly due to enhanced resident knowledge and contact [12].

Despite the extent of symptoms experienced by this population, we were unable to find any multi-symptom assessment measures validated for use in routine care as an assessment measure. Instead, we found measures that assess single symptoms or symptom groups, specifically pain, oral health signs and symptoms, multiple neuropsychiatric symptoms, depression, anxiety and psychological wellbeing, and discomfort. Assessing discomfort may alert caregivers to physical or emotional discomfort that can then be further investigated to determine the underlying cause [68]. However, content analyses of pain and discomfort measures in dementia found significant overlap resulting in poor sensitivity in assessing these constructs [69], a finding supported by our results with pain and discomfort frequently being used interchangeably. An alternative to assessing discomfort is to provide caregivers with measures to assess all common symptoms. This would facilitate a comprehensive symptom assessment, and alert caregivers to consider all common symptoms and sources of distress.

Caregivers' use of a battery of single assessments (e.g. pain, neuropsychiatric symptoms, oral health) could facilitate detection and monitoring of common symptoms, but is unlikely to be feasible for regular and frequent use due to the time taken to complete multiple measures. Palliative or end-of-life measures, such as the Symptom Management at the End of Life in Dementia [70] or the Palliative care Outcome Scale [71] could provide a brief yet comprehensive assessment of common physical, psychological, and other distressing (such as agitation) [70] symptoms to support detection and management of symptoms in care. The former was developed to measure outcomes and evaluate end-of-life care in dementia and has been extensively evaluated [70, 72–74], although predominantly after the death of the resident. It incorporates nine symptoms in people dying with dementia and therefore has the potential for use as a clinical assessment measure for people in the dying phase. The Palliative care Outcome Scale was developed for a non-dementia population but has sound psychometric properties and is used across settings to support clinical care [75]. It has been used to assess symptoms and the quality of palliative care to nursing home patients with and without dementia [76] and found to have the potential to identify areas of care that require addressing. Nonetheless, there was a high level of missing scores for some items (≤59.8 %) in the dementia subgroup, suggesting adaptation is required for this population [76]. Results of a qualitative study suggest that such multi-symptom measures used in routine care may require provision of proxy-observed behaviors or signs to assess verbally-compromised residents with dementia [77]. Use of a single multi-symptom measure may not provide a detailed assessment of each symptom. However, multi-symptom measures may support comprehensive assessment of symptoms with minimal time burden and, if required, inform requirement for further assessment or prompt referral to health professionals.

The second major finding from our study is the lack of assessment measures to assess common symptoms. The clinical challenges and importance of accurately assessing pain in this population is apparent by substantial development in pain measures, evidenced by a recent meta-review [78]. As a consequence, we found pain measures have the strongest psychometric evidence. Nonetheless, despite the prevalence of other common symptoms in residents with dementia, such as nausea, constipation, and dyspnea, we were unable to identify any measures to assess these. With further evaluation, the Respiratory Distress Observation Scale-Family (RDOS-Family) [79] has potential to be an important measure for detecting dyspnea in long-term care residents with dementia. The original RDOS was designed for cognitively impaired adults unable to self-report but required clinical expertise to administer [80]. RDOS-Family is family caregiver self-administered based on observations with a 20-minute training provided. It has good inter-rater reliability (ICC = 0.71) between family and trained research assistants when used with patients hospitalized for conditions with dyspnea.

The stringent methodological requirements of the quality criteria and the challenges of conducting research in verbally compromised people with dementia resulted in no measures achieving positive ratings for all psychometric properties in the review. In particular, this review shows that detecting depression in people unable to self-report in this setting is challenging and that caregivers' use of observational signs may be insufficient to assess depression. Self-report, or a clinician-administered observer-rated scale for those with moderate to severe dementia, has been recommended for assessment of depression in nursing home residents [81]. The MDS 3.0 takes this approach with the embedded Patient Health Questionnaire-9 Observational Version designed for residents unable to self-report based on observations [82]. It is completed by trained nurse assessors through interview with a caregiver who knows the resident, thus combining clinician expertise with caregiver knowledge of the resident. The Patient Health Questionnaire-9 Observational Version demonstrated strong correlation ($r = 0.84$, $n = 48$) with trained research nurse-administered CSDD [83].

We included studies conducted in all settings and some measures therefore require further validation in long-term care settings. Where measures do not exist for symptom assessment in long-term care, this review informs selection of measures for further validation by reporting strength of psychometric properties and potential applicability in long-term care settings.

This systematic review identifies and critically appraises measures of common symptoms in the dementia population in long-term care; however, there are a number of limitations. Screening measures are used to detect diagnoses such as depression and anxiety. Studies evaluating screening measures may not have been detected or met the inclusion criteria for this study. Furthermore, the quality criteria used in this review were not developed to evaluate screening tools. However, using the same quality criteria provided consistency of appraisal across the included measures. We limited the study to English language-validated measures only and to publications in English only. This means measures not developed in English, such as the Dutch Rotterdam Elderly Pain Observation Scale [84], or translated measures, such as the German [85, 86] and Chinese [87] versions of the PAINAD, and Dutch [88, 89] and Italian [90] versions of the DS-DAT, are excluded. We recognize that

the conclusions are therefore limited to English language measures and therefore limited to English-speaking populations and cultures, with the majority of studies conducted in English-speaking countries, predominantly the United States. This means that the most established measures with the strongest international psychometric evidence that have been validated in multiple languages, countries, or cultures are not identified as such. Finally, decisions regarding whether measures met the inclusion criteria required judgement at times. To improve objectivity, those full-texts that did not clearly meet the exclusion criteria were second reviewed and a decision reached by consensus.

Conclusion

Assessment measures of pain are the best developed and have the strongest evidence of psychometric properties for use by caregivers in people with dementia. All other assessment measures require further evaluation when administered by caregivers in long-term care settings. A caregiver-completed multi-symptom measure to assess the full extent of symptoms in people with dementia is urgently required so that symptoms are detected and residents are referred when medical intervention is needed.

Availability of data and materials

The datasets supporting the conclusions of this article are included within the article and its additional files.

Additional files

Additional file 1: PRISMA checklist. (DOC 63 kb)

Additional file 2: Full search strategy – search strategy used. (DOCX 19 kb)

Additional file 3: Study details for included studies – population, setting, and who the measure was administered by. (DOCX 24 kb)

Additional file 4: Psychometric evaluation of measures – psychometric evaluation of all measures. (DOCX 24 kb)

Additional file 5: Summary of measure details, methods of administration, feasibility, and applicability in care – measure details, length of measure, time taken to complete, method of administration, any training required. (DOCX 43 kb)

Abbreviations

AARS: Apparent Affect Rating Scale; APS: Abbey Pain Scale; AER: Apparent Emotion Rating; BOHSE: Brief Oral Health Status Examination; CNPI: Checklist of Nonverbal Pain Behaviors; CSDD: Cornell Scale for Depression in Dementia; CS-GDS: Collateral Source Geriatric Depression Scale; DBS: Discomfort Behavior Scale; DS-DAT: Discomfort Scale for patients with Dementia of Alzheimer's Type; ICC: Intraclass correlation coefficient; NOPPAIN: Non-communicative Patient's Pain Assessment Instrument; NPI-Q: Neuropsychiatric Inventory-Questionnaire; OHAT: Oral Health Assessment Tool; PACSLAC: Pain Assessment Checklist for Seniors with Limited Ability to Communicate; PADE: Pain Assessment for the Dementing Elderly; PAINAD: Pain Assessment in Advanced Dementia; PBOICIE: Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders; PGCARS: Philadelphia Geriatric Center Affect Rating Scale; RDOS: Respiratory Distress Observation Scale.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CES, CJE, IJH and BD conceived and designed the study. CES conducted the literature search. CES, CJE, AEB, LAH, MD, PMK, and BD were involved in the analysis and interpretation of data. CES, CJE and BD drafted the manuscript. The study was supervised by CJE, IJH and BD. All authors read and approved the final manuscript.

Acknowledgements

BuildCARE is supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy & Rehabilitation, UK. CI: Higginson. Grant leads: Higginson, McCrone, Normand, Lawlor, Meier, Morrison. Project Co-ordinator/PI: Daveson. Study arm PIs: Pantilat, Selman, Normand, Ryan, McQuillan, Morrison, Daveson. We thank all collaborators & advisors including service-users. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara A Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J Evans, Lesley Henson, Irene J Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Lara Klass, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Susan Molony, Sean Morrison, Fliss E Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Gao Wei.

Funding

This study was part funded by Cicely Saunders International and The Atlantic Philanthropies, and part funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care Funding scheme. The Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London is part of the National Institute for Health Research (NIHR) and is a partnership between King's Health Partners, St. George's, University London, and St George's Healthcare NHS Trust. The views and opinions expressed are those of the authors and not necessarily those of the NHS, the NIHR, MRC, CCF, NETSCC, NIHR Programme Grants for Applied Research or Department of Health. The funding organizations had no role in the design of the study, and collection, analysis, and interpretation of the data, or writing of the manuscript.

Received: 18 November 2015 Accepted: 15 February 2016
Published online: 26 February 2016

References

1. Mitchell SL, Kiely DK, Hamel MB, Park PS, Morris JN, Fries BE. Estimating prognosis for nursing home residents with advanced dementia. JAMA. 2004;291:2734–40.
2. van der Steen JT. Dying with dementia: what we know after more than a decade of research. J Alzheimers Dis. 2010;22:37–55.
3. McCarthy M, Addington-Hall J, Altmann D. The experience of dying with dementia: a retrospective study. Int J Geriatr Psychiatry. 1997;12:404–9.
4. Di Giulio P, Toscani F, Villani D, Brunelli C, Gentile S, Spadin P. Dying with advanced dementia in long-term care geriatric institutions: a retrospective study. J Palliat Med. 2008;11:1023–8.
5. Lyketsos CG, Lopez O, Jones B, Fitzpatrick AL, Breitner J, DeKosky S. Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment: results from the cardiovascular health study. JAMA. 2002;288:1475–83.
6. Hanson LC, Eckert JK, Dobbs D, Williams CS, Caprio AJ, Sloane PD, et al. Symptom experience of dying long-term care residents. J Am Geriatr Soc. 2008;56:91–8.
7. Mitchell SL, Kiely DK, Hamel MB. Dying with advanced dementia in the nursing home. Arch Intern Med. 2004;164:321–6.
8. Brandt HE, Deliens L, Ooms ME, van der Steen JT, van der Wal G, Ribbe MW. Symptoms, signs, problems, and diseases of terminally ill nursing home patients: A nationwide observational study in the Netherlands. Arch Intern Med. 2005;165:314–20.
9. Mitchell SL, Teno JM, Kiely DK, Shaffer ML, Jones RN, Prigerson HG, et al. The clinical course of advanced dementia. N Engl J Med. 2009;36:1529–38.
10. Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. Br Med J. 2011;343:d4065.

11. Sourial R, McCusker J, Cole M, Abrahamowicz M. Agitation in demented patients in an acute care hospital: Prevalence, disruptiveness, and staff burden. Int Psychogeriatr. 2001;13:183–96.
12. Hendrix CC, Sakauye KM, Karabatsos G, Daigle D. The use of the Minimum Data Set to identify depression in the elderly. J Am Med Dir Assoc. 2003;4:308–12.
13. Etkind SN, Daveson BA, Kwok W, Witt J, Bausewein C, Higginson IJ, et al. Capture, transfer, and feedback of patient-centered outcomes data in palliative care populations: does it make a difference? A systematic review. J Pain Symptom Manage. 2015;49:611–24.
14. Higginson IJ, Carr AJ. Using quality of life measures in the clinical setting. Br Med J. 2001;322:1297–300.
15. Slade M, Thornicroft G, Glover G. The feasibility of routine outcome measures in mental health. Soc Psychiatry Psychiatr Epidemiol. 1999;34:243–9.
16. Gitlin LN, Marx KA, Stanley IH, Hansen BR, Van Haitsma KS. Assessing neuropsychiatric symptoms in people with dementia: a systematic review of measures. Int Psychogeriatr. 2014;26:1805–48.
17. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Br Med J. 2009;339:b2535.
18. Woods B, Aguirre E, Spector AE, Orrell M. Cognitive stimulation to improve cognitive functioning in people with dementia. Cochrane Database Syst Rev. 2012;2:CD005562. doi:10.1002/14651858.CD005562.pub2.
19. Hall S, Kolliakou A, Petkova H, Froggatt K, Higginson IJ. Interventions for improving palliative care for older people living in nursing care homes (review). Cochrane Database Syst Rev. 2011;3, CD007132. doi:10.1002/14651858.CD007132.pub2.
20. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60:34–42.
21. Bollen JC, Dean SG, Siegert RJ, Howe TE, Goodwin VA. A systematic review of measures of self-reported adherence to unsupervised home-based rehabilitation exercise programmes, and their psychometric properties. BMJ Open. 2014;4:e005044.
22. de Vet HC, Ostelo RW, Terwee CB, van der Roer N, Knol DL, Beckerman H, et al. Minimally important change determined by a visual method integrating an anchor-based and a distribution-based approach. Qual Life Res. 2007;16:131–42.
23. Streiner DL, Cairney J. What's under the ROC? An introduction to receiver operating characteristics curves. Can J Psychiatry. 2007;52:121–8.
24. Bradford A, Brenes GA, Robinson RA, Wilson N, Snow AL, Kunik ME, et al. Concordance of self- and proxy-rated worry and anxiety symptoms in older adults with dementia. J Anxiety Disord. 2013;27:125–30.
25. Burgener SC, Twigg P, Popovich A. Measuring psychological well-being in cognitively impaired persons. Dementia. 2005;4:463–85.
26. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. J Neuropsychiatry Clin Neurosci. 2000;12:233–9.
27. Logsdon RG, Teri L. Depression in Alzheimer's disease patients: caregivers as surrogate reporters. J Am Geriatr Soc. 1995;43:150–5.
28. Nitcher RL, Burke WJ, Roccaforte WH, Wengel SP. A collateral source version of the Geriatric Depression Rating Scale. Am J Geriatr Psychiatry. 1993;1:143–52.
29. Tsai PF, Beck C, Richards KC, Phillips L, Roberson PK, Evans J. The Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders (PBOICIE). Res Gerontol Nurs. 2008;1:116–22.
30. Victoroff J, Nielson K, Mungas D. Caregiver and clinician assessment of behavioral disturbances: the California Dementia Behavior Questionnaire. Int Psychogeriatr. 1997;9:155–74.
31. DeWaters T, Faut-Callahan M, McCann JJ, Paice JA, Fogg L, Hollinger-Smith L, et al. Comparison of self-reported pain and the PAINAD scale in hospitalized cognitively impaired and intact older adults after hip fracture surgery. Orthop Nurs. 2008;27:21–8.
32. Elanchenny N, Shah A. Evaluation of three nurse-administered depression rating scales on acute admission and continuing care geriatric psychiatry wards. Int J Methods Psychiatr Res. 2001;10:43–51.
33. Abbey J, Piller N, De Bellis A, Esterman A, Parker D, Giles L, et al. The Abbey pain scale: a 1-minute numerical indicator for people with end-stage dementia. Int J Palliat Nurs. 2004;10:6–13.
34. Cervo FA, Bruckenthal P, Chen JJ, Bright-Long LE, Fields S, Zhang G, et al. Pain assessment in nursing home residents with dementia: psychometric properties and clinical utility of the CNA Pain Assessment Tool (CPAT). J Am Med Dir Assoc. 2009;10:505–10.
35. Chan S, Hadjistavropoulos T, Williams J, Lints-Martindale A. Evidence-based development and initial validation of the pain assessment checklist for seniors with limited ability to communicate-II (PACSLAC-II). Clin J Pain. 2014;30:816–24.
36. Cheung G, Choi P. The use of the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) by caregivers in dementia care facilities. N Z Med J. 2008;121:21–9.
37. Kaasalainen S, Stewart N, Middleton J, Knezacek S, Hartley T, Ife C, et al. Development and evaluation of the Pain Assessment in the Communicatively Impaired (PACI) tool: part II. Int J Palliat Nurs. 2011;17:431–8.
38. Mahoney AEJ, Peters L. The Mahoney pain scale: Examining pain and agitation in advanced dementia. Am J Alzheimers Dis Other Demen. 2008;23:250–61.
39. Villanueva MR, Smith TL, Erickson JS, Lee AC, Singer CM. Pain Assessment for the Dementing Elderly (PADE): reliability and validity of a new measure. J Am Med Dir Assoc. 2003;4:1–8.
40. Chalmers JM, King PL, Spencer AJ, Wright FAC, Carter KD. The oral health assessment tool–validity and reliability. Aust Dent J. 2005;50:191–9.
41. Kayser-Jones J, Bird WF, Paul SM, Long L, Schell ES. An instrument to assess the oral health status of nursing home residents. Gerontologist. 1995;35:814–24.
42. Li Z, Jeon YH, Low LF, Chenoweth L, O'Connor DW, Beattie E, et al. Validity of the geriatric depression scale and the collateral source version of the geriatric depression scale in nursing homes. Int Psychogeriatr. 2015;27:1495–504.
43. Watson LC, Zimmerman S, Cohen LW, Dominik R. Practical depression screening in residential care/assisted living: five methods compared with gold standard diagnoses. Am J Geriatr Psychiatry. 2009;17:556–64.
44. Lawton MP, Van Haitsma K, Perkinson M, Ruckdeschel K. Observed affect and quality of life in dementia: further affirmations and problems. J Ment Health Aging. 1999;5:69–81.
45. Lints-Martindale AC, Hadjistavropoulos T, Lix LM, Thorpe L. A comparative investigation of observational pain assessment tools for older adults with dementia. Clin J Pain. 2012;28:226–37.
46. Ersek M, Herr K, Neradilek MB, Buck HG, Black B. Comparing the psychometric properties of the checklist of nonverbal pain behaviors (CNPI) and the pain assessment in advanced dementia (PAIN-AD) instruments. Pain Med. 2010;11:395–404.
47. Liu JYW, Briggs M, Closs SJ. The psychometric qualities of four observational pain tools (OPTs) for the assessment of pain in elderly people with osteoarthritic pain. J Pain Symptom Manage. 2010;40:582–98.
48. Warden V, Hurley AC, Volicer L. Development and psychometric evaluation of the Pain Assessment in Advanced Dementia (PAINAD) scale. J Am Med Dir Assoc. 2003;4:9–15.
49. Fuchs-Lacelle S, Hadjistavropoulos T. Development and preliminary validation of the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC). Pain Manag Nurs. 2004;5:37–49.
50. Kaasalainen S, Akhtar-Danesh N, Hadjistavropoulos T, Zwakhalen S, Verreault R. A comparison between behavioral and verbal report pain assessment tools for use with residents in long term care. Pain Manag Nurs. 2013;14:e106–14.
51. Hurley AC, Volicer BJ, Hanrahan PA, Houde S, Volicer L. Assessment of discomfort in advanced Alzheimer patients. Res Nurs Health. 1992;15:369–77.
52. Neville C, Ostini R. A psychometric evaluation of three pain rating scales for people with moderate to severe dementia. Pain Manag Nurs. 2014;15:798–806.
53. Feldt KS. The Checklist of Nonverbal Pain Indicators (CNPI). Pain Manag Nurs. 2000;1:13–21.
54. Horgas AL, Nichols AL, Schapson CA, Vietes K. Assessing pain in persons with dementia: relationships among the non-communicative patient's pain assessment instrument, self-report, and behavioral observations. Pain Manag Nurs. 2007;8:77–85.
55. Kaasalainen S, Crook J. A comparison of pain-assessment tools for use with elderly long-term-care residents. Can J Nurs Res. 2003;35:58–71.
56. Cummings JL. The Neuropsychiatric Inventory: assessing psychopathology in dementia patients. Neurology. 1997;48 Suppl 6:S10–6.
57. Anderson RL, Buckwalter KC, Buchanan RJ, Maas ML, Imhof SL. Validity and reliability of the Minimum Data Set Depression Rating Scale (MDSDRS) for older adults in nursing homes. Age Ageing. 2003;32:435–8.
58. Burrows AB, Morris JN, Simon SE, Hirdes JP, Phillips C. Development of a Minimum Data Set-based depression rating scale for use in nursing homes. Age Ageing. 2000;29:165–72.

59. Koehler M, Rabinowitz T, Hirdes J, Stones M, Carpenter GI, Fries BE, et al. Measuring depression in nursing home residents with the MDS and GDS: an observational psychometric study. BMC Geriatr. 2005;5:1471–2318.
60. Martin L, Poss JW, Hirdes JP, Jones RN, Stones MJ, Fries BE. Predictors of a new depression diagnosis among older adults admitted to complex continuing care: Implications for the depression rating scale (DRS). Age Ageing. 2008;37:51–6.
61. Hayes PM, Lohse D, Bernstein I. The development and testing of the Hayes and Lohse Non-Verbal Depression Scale. Clin Gerontol. 1991;10:3–13.
62. Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, et al. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry. 1998;59:22–33.
63. Kolanowski A, Hoffman L, Hofer SM. Concordance of self-report and informant assessment of emotional well-being in nursing home residents with dementia. J Gerontol. 2007;62:20–7.
64. Snyder M, Ryden MB, Shaver P, Wang J, Savik K, Gross CR, et al. The Apparent Emotion Rating Instrument: assessing affect in cognitively impaired elders. Clin Gerontol. 1998;18:17–29.
65. Lawton MP, Van Haitsma K, Klapper J. Observed affect in nursing home residents with Alzheimer's disease. J Gerontol. 1996;51B:3–14.
66. Stevenson KM, Brown RL, Dahl JL, Ward SE, Brown MS. The discomfort behavior scale: a measure of discomfort in the cognitively impaired based on the minimum data set 2.0. Res Nurs Health. 2006;29:576–87.
67. Miller J, Neelon V, Dalton J, Ng'andu N, Bailey Jr D, Layman E, et al. The assessment of discomfort in elderly confused patients: a preliminary study. J Neurosci Nurs. 1996;28:175–82.
68. Kovach CR, Noonan PE, Griffie J, Muchka S, Weissman DE. Use of the assessment of discomfort in dementia protocol. Appl Nurs Res. 2001;14:193–200.
69. van der Steen JT, Sampson EL, Van den Block L, Lord K, Vankova H, Pautex S, et al. Tools to assess pain or lack of comfort in dementia: a content analysis. J Pain Symptom Manage. 2015;50:659–75.
70. Volicer L, Hurley AC, Blasi ZV. Scales for evaluation of end-of-life care in dementia. Alzheimer Dis Assoc Disord. 2001;15:194–200.
71. Hearn J, Higginson I. Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. Qual Health Care. 1999;8:219–27.
72. Kiely DK, Shaffer ML, Mitchell SL. Scales for the evaluation of end-of-life care in advanced dementia: sensitivity to change. Alzheimer Dis Assoc Disord. 2012;26:358–63.
73. Kiely DK, Volicer L, Teno J, Jones RN, Prigerson HG, Mitchell SL. The validity and reliability of scales for the evaluation of end-of-life care in advanced dementia. Alzheimer Dis Assoc Disord. 2006;20:176–81.
74. van Soest-Poortvliet MC, van der Steen JT, Zimmerman S, Cohen LW, Klapwijk MS, Bezemer M, et al. Psychometric properties of instruments to measure the quality of end-of-life care and dying for long-term care residents with dementia. Qual Life Res. 2012;21:671–84.
75. Collins ES, Witt J, Bausewein C, Daveson BA, Higginson IJ, Murtagh FEM. A systematic review of the use of the palliative care outcome scale and the support team assessment schedule in palliative care. J Pain Symptom Manage. 2015;50:842–53.
76. Brandt HE, Deliens L, van der Steen JT, Ooms ME, Ribbe MW, van der Wal G. The last days of life of nursing home patients with and without dementia assessed with the Palliative Care Outcome Scale. Palliat Med. 2005;19:334–42.
77. Krumm N, Larkin P, Connolly M, Rode P, Elsner F. Improving dementia care in nursing homes: experiences with a palliative care symptom-assessment tool (MIDOS). Int J Palliat Nurs. 2014;20:187–92.
78. Lichtner V, Dowding D, Esterhuizen P, Closs S, Long A, Corbett A, et al. Pain assessment for people with dementia: a systematic review of systematic reviews of pain assessment tools. BMC Geriatr. 2014;14:138.
79. Campbell ML, Templin TN. RDOS-Family: a guided learning tool for layperson assessment of respiratory distress. J Palliat Med. 2014;17:982–3.
80. Campbell ML, Templin T, Walch J. A respiratory distress observation scale for patients unable to self-report dyspnea. J Palliat Med. 2010;13:285–90.
81. American Geriatrics Society and American Association for Geriatric Psychiatry. Consensus statement on improving the quality of mental health care in U.S. nursing homes: management of depression and behavioral symptoms associated with dementia. J Am Geriatr Soc. 2003;51:1287–98.
82. Saliba D, DiFilippo S, Edelen MO, Kroenke K, Buchanan J, Streim J. Testing the PHQ-9 Interview and Observational Versions (PHQ-9 OV) for MDS 3.0. J Am Med Dir Assoc. 2012;13:618–25.
83. Alexopoulos GS, Abrams RC, Young RC, Shamoian CA. Cornell Scale for Depression in Dementia. Biol Psychiatry. 1988;23:271–84.
84. Van Herk R, Van Dijk M, Tibboel D, Baar FPM, De Wit R, Duivenvoorden HJ. The Rotterdam Elderly Pain Observation Scale (REPOS): a new behavioral pain scale for non-communicative adults and cognitively impaired elderly persons. J Pain Manag. 2009;1:367–78.
85. Basler HD, Huger D, Kunz R, Luckmann J, Lukas A, Nikolaus T, et al. Assessment of pain in advanced dementia. Construct validity of the German PAINAD. Schmerz. 2006;20:519–26.
86. Schuler MS, Becker S, Kaspar R, Nikolaus T, Kruse A, Basler HD. Psychometric properties of the German 'Pain Assessment in Advanced Dementia Scale' (PAINAD-G) in nursing home residents. J Am Med Dir Assoc. 2007;8:388–95.
87. Lin PC, Lin LC, Shyu YIL, Hua MS. Chinese version of the Pain Assessment in Advanced Dementia Scale: initial psychometric evaluation. J Adv Nurs. 2010;66:2360–8.
88. van der Steen JT, Ader HJ, van Assendelft JH, Kooistra M, Passier PE, Ooms ME. [Retrospective assessment of the Dutch version of the Discomfort Scale–Dementia of Alzheimer Type (DS-DAT): is estimation sufficiently valid and reliable?]. Tijdschr Gerontol Geriatr. 2003;34:254–9 [In Dutch].
89. van der Steen JT, Ooms ME, van der Wal G, Ribbe MW. [Measuring discomfort in patients with dementia. Validity of a Dutch version of the Discomfort Scale–dementia of Alzheimer type (DS-DAT)]. Tijdschr Gerontol Geriatr. 2002;33:257–63 [In Dutch].
90. Dello Russo C, Di Giulio P, Brunelli C, Dimonte V, Villani D, Renga G, et al. Validation of the Italian version of the Discomfort Scale - Dementia of Alzheimer Type. J Adv Nurs. 2008;64:298–303.

Additional file 1: PRISMA checklist

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	supplement
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	14
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	supplement
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	supplement
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	supplement
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	11-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	15

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Page 2 of 2

Additional file 2: Full search strategy[1,2]

1. exp Dementia/
2. Delirium/
3. Wernicke Encephalopathy/
4. Delirium, Dementia, Amnestic, Cognitive Disorders/
5. dement*.mp.
6. alzheimer*.mp.
7. (lewy* adj2 bod*).mp.
8. deliri*.mp.
9. (chronic adj2 cerebrovascular).mp.
10. ("organic brain disease" or "organic brain syndrome").mp.
11. ("normal pressure hydrocephalus" and "shunt*").mp.
12. "benign senescent forgetfulness".mp.
13. (cerebr* adj2 deteriorat*).mp.
14. (cerebral* adj2 insufficient*).mp.
15. (pick* adj2 disease).mp.
16. (creutzfeldt or jcd or cjd).mp.
17. huntington*.mp.
18. binswanger*.mp.
19. korsako*.mp.
20. Long-Term Care/
21. exp Nursing Homes/
22. Assisted Living Facilities/
23. Homes for the Aged/
24. long term care.mp.
25. nursing home*.mp.
26. care home*.mp.
27. residential care home*.mp.
28. **OR/1-27**
29. Geriatric Assessment/
30. Needs Assessment/
31. Health Impact Assessment/
32. exp Nursing Assessment/
33. Symptom Assessment/
34. exp nutrition assessment/
35. Psychometrics/
36. Pain Measurement/
37. psychomet*.mp.
38. assess* instrument.mp.
39. assess* tool.mp.
40. (observ* adj5 assess*).mp.
41. **OR/29-40**
42. Palliative Care/
43. exp Terminal Care/
44. Terminally Ill/
45. Hospice Care/
46. palliative care.mp.
47. palliative treatment.mp.
48. palliative medicine.mp.
49. terminal care.mp.
50. terminally ill.mp.
51. end-of-life care.mp.
52. hospice care.mp.
53. exp Pain/
54. exp Pain Management/
55. pain.mp.
56. exp Dyspnea/

57. dyspn?ea.mp.
58. breathless*.mp.
59. Deglutition/
60. exp Deglutition Disorders/
61. swallow*.mp.
62. (swallow* adj3 problem*).mp.
63. Constipation/
64. constipat*.mp.
65. (mouth adj3 pain*).mp.
66. Toothache/
67. (dent* adj3 pain*).mp.
68. Accidental Falls/
69. fall*.mp.
70. mobil*.mp.
71. Pressure Ulcer/
72. (pressure adj3 ulcer).mp.
73. (pressure adj3 sore).mp.
74. (skin adj3 breakdown).mp.
75. exp Psychotic Disorders/
76. psychosis.mp.
77. psychotic.mp.
78. Delusions/
79. delusion*.mp.
80. Hallucinations/
81. hallucinat*.mp.
82. Depression/
83. depress*.mp.
84. exp Depressive Disorder/
85. exp Anxiety/
86. exp Anxiety Disorders/
87. anxiety.mp.
88. anxious.mp.
89. "Quality of Life"/
90. quality of life.mp.
91. qol.mp.
92. distress.mp.
93. wellbeing.mp.
94. "Activities of Daily Living"/
95. ADL*.mp.
96. activities of daily living.mp.
97. Vomiting/
98. Nausea/
99. vomi*.mp.
100. nausea.mp.
101. emesis.mp.
102. exp Sleep/
103. (sleep adj3 disorder*).mp.
104. **OR/42-103**
105. **28 and 41 and 104**

References

1. Woods B, Aguirre E, Spector AE, Orrell M. Cognitive stimulation to improve cognitive functioning in people with dementia. Cochrane Database Syst Rev 2012, 2:CD005562. doi: 005510.001002/14651858.CD14005562.pub14651852.
2. Hall S, Kolliakou A, Petkova H, Froggatt K, Higginson IJ. Interventions for improving palliative care for older people living in nursing care homes (review). Cochrane Database Syst Rev 2011(3):CD007132. doi:007110.001002/14651858.CD14007132.pub14651852.

Additional file 3: Study details of included studies

Lead Author and date	Measure	Setting	Population	Measure administered by
Abbey 2004 [1]	APS	Residential aged care facilities in Australia	Phase 1: 52 residents with end- or late stage dementia Phase 2: 61 residents	Registered nurses Enrolled nurses Nursing assistants
Anderson 2003 [2]	MDSDRS	Nursing homes in US	Residents aged ≥60 Baseline: n=145 3 months: n=95 21% diagnosis of dementia	Nursing home staff
Bradford 2013 [3]	GAI-Collateral PSWQ-A-Collateral	Neurology, geriatrics and psychiatry clinics and dementia care day centers in US	People aged ≥50 with diagnosis of dementia and anxiety symptoms N=41	Collateral (usually family)
Burgener 2005 [4]	PWB-CIP	Dementia diagnostic centers in US	People with diagnosis of dementia within 1 year Baseline: n=96 18 months: n=73	Primary caregiver (usually family)
Burrows 2000 [5]	MDSDRS	Nursing homes in US	Residents along full spectrum of cognition and function Total: n=108 Derivation: n=81 Validation: n=27	Nursing home nurses
Cervo 2009 [6]	CPAT	Long-term care facilities in US	Residents with diagnosis of dementia, MMSE≤19, GDS≥5 N=145	CNA direct caregivers
Chalmers 2005 [7]	OHAT	Residential aged care facilities in Australia	Residents Baseline: n=534 All study phases: n=455 56.5% diagnosis of dementia	Personal care attendants, registered nurses, enrolled nurses and nurse assistants
Chan 2014 [8]	PACSLAC-II	Long-term care facilities in Canada	Residents with dementia N=124	Long-term care staff
Cheung 2008 [9]	PACSLAC	Specialist dementia rest homes in New Zealand	Stable residents with dementia N=52	Caregivers working in the rest homes
DeWaters 2008 [10]	PAINAD	Orthopaedic unit of metropolitan hospital in US	Patients admitted for surgical repair of hip fracture, aged ≥65, cognitively impaired and intact Total: n=25 Cognitively intact: n=13 Cognitively impaired: n=12	Masters'-prepared nurses working as research assistants and principal investigator
Elanchenny 2001 [11]	DSS DDMS CSDD	Acute admission and continuing care teaching hospital geriatric psychiatry wards in UK	All inpatients at the time of the study Total: n=58 Dementia: n=43	Experienced staff nurses
Ersek 2010 [12]	CNPI PAINAD	Nursing homes in US	Residents aged ≥65 with moderate to severe pain at baseline, nonverbal or unable to provide reliable self-report N=60	Trained research assistants

Lead Author and date	Measure	Setting	Population	Measure administered by
Feldt 2000 [13]	CNPI	Hospitals in US	Hip fracture patients aged ≥65 Total: n=83 Cognitively intact: n=34 Cognitively impaired: n=49	Gerontological nurse practitioners with Master's degrees
Fuchs-Lacelle 2004 [14]	PACSLAC	Long-term care facilities in Canada	Measures completed on residents with cognitive impairments and limited ability to communicate but residents not recruited to the study	Registered nurses and registered psychiatric nurses
Hayes 1991 [15]	Hayes and Lohse Non-Verbal Depression Scale	Nursing home in US	Sample 1: non-verbal residents (n=30) Sample 2: cognitively intact residents (n=30) Sample 3: 102 residents Sample 4: 72 residents	Registered nurses and social workers
Horgas 2007 [16]	NOPPAIN	Assisted living facilities, skilled nursing facilities, retirement apartments in US	Residents with range of cognitive abilities Total sample: n=40 Cognitively intact: n=20 Cognitively impaired: n=20	Undergraduate honors nursing students
Hurley 1992 [17]	DS-DAT	Long-term care units of Department of Veterans Affairs hospitals in US	Residents with dementia Study 2:n=68 Study 3: n=82	Study investigator Nurses with graduate degrees
Kaasalainen 2003 [18]	PACI	Long-term care facility in Canada	Residents aged ≥65 Total: n=130 Cognitively intact: n=20 Mildly cognitively impaired: n=30 Moderately cognitively impaired: n=40 Extremely cognitively impaired: n=40	Study investigator and research assistant
Kaasalainen 2011 [19]	PACI	Long-term care/ complex continuing care facility in Canada	Residents aged 65-94 with diagnosis of dementia and secondary pain-related diagnosis N=14	Four study investigators from across disciplines Long-term care staff (special care aides, registered nurses, therapists)
Kaasalainen 2013 [20]	PACI PACSLAC	Long-term care homes, providing nursing and personal care in Canada	Residents with and without dementia Total sample: n=338 49% diagnosis of dementia	Research assistants
Kaufer 2000 [21]	NPI-Q	Research Center Memory Disorders and Treatment Clinics	People with probable and possible Alzheimer's disease	Caregiver-informants (usually family)

Lead Author and date	Measure	Setting	Population	Measure administered by
Kayser-Jones 1995 [22]	BOHSE	Nursing home in US	Residents aged ≥50 N=100 18% no or mildly cognitively impaired, 34% moderately cognitively impaired, 48% severely cognitively impaired	Registered nurses, licensed vocational nurses, certified nursing assistants
Koehler 2005 [23]	MDSDRS	Nursing homes in US	Residents Total: n=704 Cognitively intact: n=209 Cognitively impaired: n=495	MDS assessors
Kolanowski 2007 [24]	PGCARS	Nursing home in US	Residents with dementia N=31	Trained video raters
Lawton 1999 [25]	AARS	Nursing home in US	Study 1: residents with dementia Study 2 (minimal training): Mild dementia: n=39 Severe dementia: n=40 Study 2 (enhanced training): Mild to severe cognitive impairment: n=180	Study 1: trained research assistants Study 2: certified nursing assistants
Li 2015 [26]	CS-GDS	Nursing homes in Australia	Residents Total: n=88 Not or mild cognitively impairment: n=42 Moderate to moderately severe cognitive impairment: n=27 Severe to very severe cognitive impairment: n=19	Caregiver staff providing ongoing care to resident or family member visiting frequently
Lints-Martindale 2012 [27]	CNPI PACSLAC PADE PAINAD NOPPAIN	Long-term care facilities in Canada	Residents with diagnosis of dementia N=124	Trained research assistants
Liu 2010 [28]	PAINAD APS PACSLAC DS-DAT	Nursing homes in Hong Kong	Residents aged ≥65 with diagnosed osteoarthritis Total: n=124 Cognitively intact: n=62 Cognitively impaired: n=62	Investigator and trained research assistants
Logsdon 1995 [29]	Modified GDS Modified BDI Modified CESD	Clinic and Alzheimer's disease research center in US	People with dementia N=76	Caregivers (usually family)
Mahoney 2008 [30]	MPS	Nursing homes in Australia	Residents with advanced dementia N=112	Registered nurses and nursing assistants
Martin 2008 [31]	MDSDRS	Complex continuing care hospitals in Canada	Residents aged ≥65, very severe dementia excluded, without diagnosis of depression on admission N=7,818 (26.6% diagnosis of dementia)	MDS assessors
Neville 2014 [32]	APS Doloplus-2 CNPI	Residential aged care facilities in Australia	Residents with diagnosis of dementia N=157	Nurses

Lead Author and date	Measure	Setting	Population	Measure administered by
Nitcher 1993 [33]	CS-GDS	Outpatient geriatric assessment center in US	Patients evaluated at the center N=170 Cognitively intact: n=61 Cognitively impaired: n=109	Collateral (usually family)
Snyder 1998 [34]	AER	Nursing homes in US	Newly-admitted residents N=312 No or minimal cognitive impairment: n=202 Severe cognitive impairment: n=107	Investigators and research assistants
Stevenson 2006 [35]	DBS	Nursing homes in US	Moderate to severely cognitively impaired residents N=29,120	MDS assessor
Tsai 2008 [36]	PBOICIE	Study 3: senior health clinic in US	Study 2: people aged ≥60 with severe cognitive impairment and diagnosis of osteoarthritis N=8 Study 3: cognitively intact people aged ≥60 with diagnosis of osteoarthritis	Research assistants
Victoroff 1997 [37]	CDBQ	Outpatient dementia diagnostic and treatment centers in US	People with cognitive complaints Total: 258 Diagnosed dementia: 245 No dementia: 13	Primary caregivers (usually family)
Villanueva 2003 [38]	PADE	Long-term care facilities (skilled nursing facilities and dementia assisted-living facility	Residents with diagnosis of dementia Study 1: n=25 Study 2: n=40	Caregiver staff
Warden 2003 [39]	PAINAD	Dementia special care unit in US	Residents with a diagnosis of dementia and inability to report pain or discomfort N=44	Dementia special care unit professional nurses and master's level social work intern and clinical staff
Watson 2009 [40]	CSDD-M-LTCS	Residential care/ assisted living settings in US	Residents aged ≥65 with range of cognitive abilities N=112	Caregiver staff predominantly nursing assistants

APS: Abbey Pain Scale, MDSDRS: Minimum Data Set Depression Rating Scale, GAI-Collateral: Geriatric Anxiety Inventory-Collateral, PSWQ-A-Collateral: Penn State Worry Questionnaire –Abbreviated-Collateral, PWB-CIP: Psychological Wellbeing in Cognitively Impaired Persons, CPAT: CNA Pain Assessment Tool, OHAT: Oral Health Assessment Tool, PACSLAC: Pain Assessment Checklist for Seniors with Limited Ability to Communicate, PAINAD: Pain Assessment in Advanced Dementia, DSS: Depressive Signs Scale, DDMS: Depression in Dementia Mood Scale, CSDD: Cornell Scale for Depression in Dementia, CNPI: Checklist of Nonverbal Pain Behaviors, NOPPAIN: Non-communicative Patient's Pain Assessment Instrument, DS-DAT: Discomfort Scale for patients with Dementia of Alzheimer's Type, PACI: Pain Assessment in Communicatively Impaired, NPI-Q: Neuropsychiatric Inventory-Questionnaire, BOHSE: Brief Oral Health Status Examination, PGCARS: Philadelphia Geriatric Center Affect Rating Scale, AARS: Apparent Affect Rating Scale, CS-GDS: Collateral Geriatric Depression Scale, PADE: Pain Assessment for the Dementing Elderly, BDI: Beck

Depression Inventory, CESD: Center for Epidemiological Studies Depression Scale, MPS: Mahoney Pain Scale, AER: Apparent Emotion Rating, DBS: Discomfort Behavior Scale, PBOICIE: Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders, CDBQ: California Dementia Behavior Questionnaire

MMSE: Mini Mental State Examination, GDS: Global Deterioration Scale

References

1. Abbey J, Piller N, De Bellis A, Esterman A, Parker D, Giles L, et al. The Abbey pain scale: a 1-minute numerical indicator for people with end-stage dementia. Int J Palliat Nurs 2004, 10:6-13.
2. Anderson RL, Buckwalter KC, Buchanan RJ, Maas ML, Imhof SL. Validity and reliability of the Minimun Data Set Depression Rating Scale (MDSDRS) for older adults in nursing homes. Age Ageing 2003, 32:435-438.
3. Bradford A, Brenes GA, Robinson RA, Wilson N, Snow AL, Kunik ME, et al. Concordance of self- and proxy-rated worry and anxiety symptoms in older adults with dementia. J Anxiety Disord 2013, 27:125-130.
4. Burgener SC, Twigg P, Popovich A. Measuring psychological well-being in cognitively impaired persons. Dementia 2005, 4:463-485.
5. Burrows AB, Morris JN, Simon SE, Hirdes JP, Phillips C. Development of a Minimum Data Set-based depression rating scale for use in nursing homes. Age Ageing 2000, 29:165-172.
6. Cervo FA, Bruckenthal P, Chen JJ, Bright-Long LE, Fields S, Zhang G. Pain assessment in nursing home residents with dementia: psychometric properties and clinical utility of the CNA Pain Assessment Tool (CPAT). J Am Med Dir Assoc 2009, 10:505-510.
7. Chalmers JM, King PL, Spencer AJ, Wright FAC, Carter KD. The oral health assessment tool--validity and reliability. Aust Dent J 2005, 50:191-199.
8. Chan S, Hadjistavropoulos T, Williams J, Lints-Martindale A. Evidence-based development and initial validation of the pain assessment checklist for seniors with limited ability to communicate-II (PACSLAC-II). Clin J Pain 2014, 30:816-824.
9. Cheung G, Choi P. The use of the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) by caregivers in dementia care facilities. N Z Med J 2008, 121:21-29.
10. DeWaters T, Faut-Callahan M, McCann JJ, Paice JA, Fogg L, Hollinger-Smith L, et al. Comparison of self-reported pain and the PAINAD scale in hospitalized cognitively impaired and intact older adults after hip fracture surgery. Orthop Nurs 2008, 27:21-28.

11. Elanchenny N, Shah A. Evaluation of three nurse-administered depression rating scales on acute admission and continuing care geriatric psychiatry wards. Int J Methods Psychiatr Res 2001, 10:43-51.
12. Ersek M, Herr K, Neradilek MB, Buck HG, Black B. Comparing the psychometric properties of the checklist of nonverbal pain behaviors (CNPI) and the pain assessment in advanced dementia (PAIN-AD) instruments. Pain Med 2010, 11:395-404.
13. Feldt KS. The Checklist of Nonverbal Pain Indicators (CNPI). Pain Manag Nurs 2000, 1:13-21.
14. Fuchs-Lacelle S, Hadjistavropoulos T. Development and preliminary validation of the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC). Pain Manag Nurs 2004, 5:37-49.
15. Hayes PM, Lohse D, Bernstein I. The development and testing of the Hayes and Lohse Non-Verbal Depression Scale. Clin Gerontol 1991, 10:3-13.
16. Horgas AL, Nichols AL, Schapson CA, Vietes K. Assessing pain in persons with dementia: relationships among the non-communicative patient's pain assessment instrument, self-report, and behavioral observations. Pain Manag Nurs 2007, 8:77-85.
17. Hurley AC, Volicer BJ, Hanrahan PA, Houde S, Volicer L. Assessment of discomfort in advanced Alzheimer patients. Res Nurs Health 1992, 15:369-377.
18. Kaasalainen S, Crook J. A comparison of pain-assessment tools for use with elderly long-term-care residents. Can J Nurs Res 2003, 35:58-71.
19. Kaasalainen S, Stewart N, Middleton J, Knezacek S, Hartley T, Ife C, et al. Development and evaluation of the Pain Assessment in the Communicatively Impaired (PACI) tool: part II. Int J Palliat Nurs 2011, 17:431-438.
20. Kaasalainen S, Akhtar-Danesh N, Hadjistavropoulos T, Zwakhalen S, Verreault R. A comparison between behavioral and verbal report pain assessment tools for use with residents in long term care. Pain Manag Nurs 2013, 14:e106-e114.
21. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. J Neuropsychiatry Clin Neurosci 2000, 12:233-239.
22. Kayser-Jones J, Bird WF, Paul SM, Long L, Schell ES. An instrument to assess the oral health status of nursing home residents. Gerontologist 1995, 35:814-824.

23. Koehler M, Rabinowitz T, Hirdes J, Stones M, Carpenter GI, Fries BE, et al. Measuring depression in nursing home residents with the MDS and GDS: An observational psychometric study. BMC Geriatr 2005, 5:1471-2318.
24. Kolanowski A, Hoffman L, Hofer SM. Concordance of self-report and informant assessment of emotional well-being in nursing home residents with dementia. J Gerontol 2007, 62:20-27.
25. Lawton MP, Van Haitsma K, Perkinson M, Ruckdeschel K. Observed affect and quality of life in dementia: Further affirmations and problems. J Ment Health Aging 1999, 5:69-81.
26. Li Z, Jeon YH, Low LF, Chenoweth L, O'Connor DW, Beattie E, et al. Validity of the geriatric depression scale and the collateral source version of the geriatric depression scale in nursing homes. Int Psychogeriatr 2015, 27:1495-1504.
27. Lints-Martindale AC, Hadjistavropoulos T, Lix LM, Thorpe L. A comparative investigation of observational pain assessment tools for older adults with dementia. Clin J Pain 2012, 28:226-237.
28. Liu JYW, Briggs M, Closs SJ. The psychometric qualities of four observational pain tools (OPTs) for the assessment of pain in elderly people with osteoarthritic pain. J Pain Symptom Manage 2010, 40:582-598.
29. Logsdon RG, Teri L. Depression in Alzheimer's disease patients: Caregivers as surrogate reporters. J Am Geriatr Soc 1995, 43:150-155.
30. Mahoney AEJ, Peters L. The Mahoney pain scale: Examining pain and agitation in advanced dementia. Am J Alzheimers Dis Other Demen 2008, 23:250-261.
31. Martin L, Poss JW, Hirdes JP, Jones RN, Stones MJ, Fries BE. Predictors of a new depression diagnosis among older adults admitted to complex continuing care: Implications for the depression rating scale (DRS). Age Ageing 2008, 37:51-56.
32. Neville C, Ostini R. A psychometric evaluation of three pain rating scales for people with moderate to severe dementia. Pain Manag Nurs 2014, 15:798-806.
33. Nitcher RL, Burke WJ, Roccaforte WH, Wengel SP. A collateral source version of the Geriatric Depression Rating Scale. Am J Geriatr Psychiatry 1993, 1:143-152.
34. Snyder M, Ryden MB, Shaver P, Wang J, Savik K, Gross CR, et al. The Apparent Emotion Rating Instrument: assessing affect in cognitively impaired elders. Clin Gerontol 1998, 18:17-29.

35. Stevenson KM, Brown RL, Dahl JL, Ward SE, Brown MS. The discomfort behavior scale: a measure of discomfort in the cognitively impaired based on the minimum data set 2.0. Res Nurs Health 2006, 29:576-587.

36. Tsai PF, Beck C, Richards KC, Phillips L, Roberson PK, Evans J. The Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders (PBOICIE). Res Gerontol Nurs 2008, 1:116-122.

37. Victoroff J, Nielson K, Mungas D. Caregiver and clinician assessment of behavioral disturbances: the California Dementia Behavior Questionnaire. Int Psychogeriatr 1997, 9:155-174.

38. Villanueva MR, Smith TL, Erickson JS, Lee AC, Singer CM. Pain Assessment for the Dementing Elderly (PADE): reliability and validity of a new measure. J Am Med Dir Assoc 2003, 4:1-8.

39. Warden V, Hurley AC, Volicer L. Development and Psychometric Evaluation of the Pain Assessment in Advanced Dementia (PAINAD) Scale. J Am Med Dir Assoc 2003, 4:9-15.

40. Watson LC, Zimmerman S, Cohen LW, Dominik R. Practical depression screening in residential care/assisted living: five methods compared with gold standard diagnoses. Am J Geriatr Psychiatry 2009, 17:556-564.

Additional file 4: Psychometric evaluation of measures

Name of measures	Content validity	Internal consistency	Criterion validity	Construct validity	Reproducibility		Responsiveness	Floor and ceiling effects	Interpretability
					Agreement	Reliability			
Pain									
APS [1]	+	?	?	0	0	?	?	0	0
APS [2]	0	+	-	+	0	+	0	0	?
APS [3]	0	+	0	?	0	+	0	0	0
CNPI [4]	?	?	?	?	0	?	0	?	0
CNPI [5]	0	?	0	?	0	-	0	-	0
CNPI [6]	0	?	?	+	0	+	0	0	0
CNPI [3]	0	+	0	?	0	-	0	0	0
CPAT [7]	+	?	-	?	0	?	0	0	0
Doloplus-2 [3]	0	+	0	?	0	+	0	0	0
MPS [8]	+	?	0	?	0	?	0	0	0
NOPPAIN [9]	+	?	?	?	0	?	0	0	0
NOPPAIN [6]	0	?	?	+	0	+	0	0	0
PAINAD [10]	+	?	0	?	0	?	0	-	?
PAINAD [11]	0	?	0	?	0	?	0	?	0
PAINAD [5]	?	?	0	?	0	-	0	-	0
PAINAD [2]	0	+	-	+	0	+	0	0	?
PAINAD [6]	0	?	?	+	0	+	0	0	0
PACSLAC [12]	+	?	0	?	0	0	0	0	0
PACSLAC [13]	0	0	?	?	0	?	0	0	0
PACSLAC [2]	0	?	-	+	0	+	0	0	?
PACSLAC [6]	0	?	?	+	0	+	0	0	0
PACSLAC [14]	0	0	-	?	0	+	0	0	0
PACSLAC-II [15]	+	?	0	+	0	-	0	0	0
PACI [16]	?	0	?	0	0	?	0	0	0
PACI [17]	+	0	0	?	0	-	0	0	0
PACI [14]	0	0	-	?	0	-	0	0	0
PADE [18]	+	?	?	?	0	?	0	0	0
PADE [6]	0	?	?	+	0	+	0	0	0
PBOICIE [19]	+	?	?	?	0	?	0	0	?

Name of measures	Content validity	Internal consistency	Criterion validity	Construct validity	Reproducibility		Responsiveness	Floor and ceiling effects	Interpretability
					Agreement	Reliability			
Oral health signs and symptoms									
BOHSE [20]	+	0	0	0	0	?	0	0	0
OHAT [21]	+	0	?	0	0	+	?	-	0
Neuropsychiatric symptoms									
NPI-Q [22]	0	0	+	?	0	?	0	0	0
CDBQ [23]	+	?	0	?	0	?	0	0	0
Depression									
BDI-modified [24]	0	?	-	?	0	0	0	0	0
CESD– modified [24]	0	?	+	?	0	0	0	0	0
CSDD – modified [25]	0	?	?	?	0	?	0	0	0
CSDD-M-LTCS [26]	+	0	-	0	0	-	0	0	0
DDMS [25]	0	?	?	?	0	?	0	0	0
DSS [25]	0	?	?	?	0	?	0	0	0
GDS-Collateral source [26]	0	0	-	?	0	?	0	0	0
GDS-Collateral source [27]	+	0	?	0	0	?	0	0	0
GDS-modified [24]	0	?	+	?	0	0	0	0	0
Hayes and Lohse Non-verbal Scale [29]	+	?	0	?	0	?	0	0	?
MDSDRS [30]	?	?	+	0	0	0	0	0	0
MDSDRS [31]	0	?	-	0	0	-	0	-	0
MDSDRS [32]	0	?	0	?	0	0	0	-	0
MDSDRS [33]	?	?	?	0	0	0	0	0	0
Anxiety									
GAI [34]	0	?	?	0	0	?	0	0	0
PSWQ-A [34]	0	?	?	0	0	?	0	0	0
Psychological wellbeing									
PGCARS [35]	0	0	0	?	0	?	0	0	0

Name of measures	Content validity	Internal consistency	Criterion validity	Construct validity	Reproducibility		Responsiveness	Floor and ceiling effects	Interpretability
					Agreement	Reliability			
PWB-CIP [36]	+	?	0	?	0	0	0	0	0
AARS [37]	0	0	0	?	0	-	0	0	0
AER [38]	-	?	0	-	0	?	0	0	?
Discomfort									
DBS [39]	?	+	0	?	0	0	0	-	?
DS-DAT[40]	+	?	0	?	0	?	0	0	0
DS-DAT [2]	-	-	-	+	0	+	0	0	?

APS: Abbey Pain Scale, CNPI: Checklist of Nonverbal Behaviors, CPAT: CNA Pain Assessment Tool, MPS: Mahoney Pain Assessment Tool, NOPPAIN: Non-communicative Patient's Pain Assessment Instrument, PAINAD: Pain Assessment in Advanced Dementia, PACSLAC: Pain Assessment Checklist for Seniors with Limited Ability to Communicate, PACI: Pain Assessment in Communicatively Impaired, PADE: Pain Assessment for Dementing Elderly, PBOICIE: Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders, BOHSE: Brief Oral Health Status Examination, OHAT: Oral Health Assessment Tool, NPI-Q: Neuropsychiatric Inventory Questionnaire, CDBQ: California Dementia Behavior Questionnaire, BDI-modified: Beck Depression Inventory – modified, CESD-Modified: Center for Epidemiologic Studies Depression Scale – modified, CSDD-modified: Cornell Scale for Depression in Dementia, CSDD-M-LTCS: Cornell Scale for Depression in Dementia Modified for use by Long Term Care Staff, DDMS-modified: Depression in Dementia Mood Scale – modified, DSS-modified: Depression Signs Scale – modified, GDS: Geriatric Depression Scale, MDSDRS: Minimum Data Set Depression Rating Scale, GAI – modified: Geriatric Anxiety Inventory – modified, PSWQ-A-modified: Penn State Worry Questionnaire – Abbreviated – modified, PGCARS: Philadelphia Geriatric Center Affect Rating Scale, PWB-CIP: Psychological Wellbeing in Cognitively Impaired Persons, AARS: Apparent Affect Rating Scale, AER: Apparent Emotion Rating Instrument, DBS: Discomfort Behavior Scale, DS-DAT: Discomfort Scale for patients with Dementia of Alzheimer's Type

+ a positive rating indicates strong psychometric properties according to quality criteria using adequate design and method

? Intermediate rating indicates some but not all aspects of psychometric property is positive, or there is doubt about design and method used

- a negative rating indicates psychometric property does not meet criteria despite adequate design and method used

0 No information provided in the paper

References:

1. Abbey J, Piller N, De Bellis A, Esterman A, Parker D, Giles L, et al. The Abbey pain scale: a 1-minute numerical indicator for people with end-stage dementia. Int J Palliat Nurs 2004, 10:6-13.
2. Liu JYW, Briggs M, Closs SJ. The psychometric qualities of four observational pain tools (OPTs) for the assessment of pain in elderly people with osteoarthritic pain. J Pain Symptom Manage 2010, 40:582-598.
3. Neville C, Ostini R. A psychometric evaluation of three pain rating scales for people with moderate to severe dementia. Pain Manag Nurs 2014, 15:798-806.
4. Feldt KS. The Checklist of Nonverbal Pain Indicators (CNPI). Pain Manag Nurs 2000, 1:13-21.
5. Ersek M, Herr K, Neradilek MB, Buck HG, Black B. Comparing the psychometric properties of the checklist of nonverbal pain behaviors (CNPI) and the pain assessment in advanced dementia (PAIN-AD) instruments. Pain Med 2010, 11:395-404.
6. Lints-Martindale AC, Hadjistavropoulos T, Lix LM, Thorpe L. A comparative investigation of observational pain assessment tools for older adults with dementia. Clin J Pain 2012, 28:226-237.
7. Cervo FA, Bruckenthal P, Chen JJ, Bright-Long LE, Fields S, Zhang G, et al. Pain assessment in nursing home residents with dementia: psychometric properties and clinical utility of the CNA Pain Assessment Tool (CPAT). J Am Med Dir Assoc 2009, 10:505-510.
8. Mahoney AEJ, Peters L. The Mahoney pain scale: Examining pain and agitation in advanced dementia. Am J Alzheimers Dis Other Demen 2008, 23:250-261.
9. Horgas AL, Nichols AL, Schapson CA, Vietes K. Assessing pain in persons with dementia: relationships among the non-communicative patient's pain assessment instrument, self-report, and behavioral observations. Pain Manag Nurs 2007, 8:77-85.
10. Warden V, Hurley AC, Volicer L. Development and Psychometric Evaluation of the Pain Assessment in Advanced Dementia (PAINAD) Scale. J Am Med Dir Assoc 2003, 4:9-15.
11. DeWaters T, Faut-Callahan M, McCann JJ, Paice JA, Fogg L, Hollinger-Smith L, et al. Comparison of self-reported pain and the PAINAD scale in hospitalized cognitively impaired and intact older adults after hip fracture surgery. Orthop Nurs 2008, 27:21-28.

12. Fuchs-Lacelle S, Hadjistavropoulos T. Development and preliminary validation of the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC). Pain Manag Nurs 2004, 5:37-49.
13. Cheung G, Choi P. The use of the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) by caregivers in dementia care facilities. N Z Med J 2008, 121:21-29.
14. Kaasalainen S, Akhtar-Danesh N, Hadjistavropoulos T, Zwakhalen S, Verreault R. A comparison between behavioral and verbal report pain assessment tools for use with residents in long term care. Pain Manag Nurs 2013, 14:e106-e114.
15. Chan S, Hadjistavropoulos T, Williams J, Lints-Martindale A. Evidence-based development and initial validation of the pain assessment checklist for seniors with limited ability to communicate-II (PACSLAC-II). Clin J Pain 2014, 30:816-824.
16. Kaasalainen S, Crook J. A comparison of pain-assessment tools for use with elderly long-term-care residents. Can J Nurs Res 2003, 35:58-71.
17. Kaasalainen S, Stewart N, Middleton J, Knezacek S, Hartley T, Ife C, et al. Development and evaluation of the Pain Assessment in the Communicatively Impaired (PACI) tool: part II. Int J Palliat Nurs 2011, 17:431-438.
18. Villanueva MR, Smith TL, Erickson JS, Lee AC, Singer CM. Pain Assessment for the Dementing Elderly (PADE): reliability and validity of a new measure. J Am Med Dir Assoc 2003, 4:1-8.
19. Tsai PF, Beck C, Richards KC, Phillips L, Roberson PK, Evans J. The Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders (PBOICIE). Res Gerontol Nurs 2008, 1:116-122.
20. Kayser-Jones J, Bird WF, Paul SM, Long L, Schell ES. An instrument to assess the oral health status of nursing home residents. Gerontologist 1995, 35:814-824.
21. Chalmers JM, King PL, Spencer AJ, Wright FAC, Carter KD. The oral health assessment tool--validity and reliability. Aust Dent J 2005, 50:191-199.
22. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. J Neuropsychiatry Clin Neurosci 2000, 12:233-239.

23. Victoroff J, Nielson K, Mungas D. Caregiver and clinician assessment of behavioral disturbances: the California Dementia Behavior Questionnaire. Int Psychogeriatr 1997, 9:155-174.
24. Logsdon RG, Teri L. Depression in Alzheimer's disease patients: Caregivers as surrogate reporters. J Am Geriatr Soc 1995, 43:150-155.
25. Elanchenny N, Shah A. Evaluation of three nurse-administered depression rating scales on acute admission and continuing care geriatric psychiatry wards. Int J Methods Psychiatr Res 2001, 10:43-51.
26. Watson LC, Zimmerman S, Cohen LW, Dominik R. Practical depression screening in residential care/assisted living: five methods compared with gold standard diagnoses. Am J Geriatr Psychiatry 2009, 17:556-564.
27. Nitcher RL, Burke WJ, Roccaforte WH, Wengel SP. A collateral source version of the Geriatric Depression Rating Scale. Am J Geriatr Psychiatry 1993, 1:143-152.
28. Li Z, Jeon YH, Low LF, Chenoweth L, O'Connor DW, Beattie E, et al. Validity of the geriatric depression scale and the collateral source version of the geriatric depression scale in nursing homes. Int Psychogeriatr 2015, 27:1495-1504.
29. Hayes PM, Lohse D, Bernstein I. The development and testing of the Hayes and Lohse Non-Verbal Depression Scale. Clin Gerontol 1991, 10:3-13.
30. Burrows AB, Morris JN, Simon SE, Hirdes JP, Phillips C. Development of a Minimum Data Set-based depression rating scale for use in nursing homes. Age Ageing 2000, 29:165-172.
31. Anderson RL, Buckwalter KC, Buchanan RJ, Maas ML, Imhof SL. Validity and reliability of the Minimun Data Set Depression Rating Scale (MDSDRS) for older adults in nursing homes. Age Ageing 2003, 32:435-438.
32. Koehler M, Rabinowitz T, Hirdes J, Stones M, Carpenter GI, Fries BE, et al. Measuring depression in nursing home residents with the MDS and GDS: An observational psychometric study. BMC Geriatr 2005, 5:1471-2318.
33. Martin L, Poss JW, Hirdes JP, Jones RN, Stones MJ, Fries BE. Predictors of a new depression diagnosis among older adults admitted to complex continuing care: Implications for the depression rating scale (DRS). Age Ageing 2008, 37:51-56.

34. Bradford A, Brenes GA, Robinson RA, Wilson N, Snow AL, Kunik ME, et al. Concordance of self- and proxy-rated worry and anxiety symptoms in older adults with dementia. J Anxiety Disord 2013, 27:125-130.
35. Kolanowski A, Hoffman L, Hofer SM. Concordance of self-report and informant assessment of emotional well-being in nursing home residents with dementia. J Gerontol 2007, 62:20-27.
36. Burgener SC, Twigg P, Popovich A. Measuring psychological well-being in cognitively impaired persons. Dementia 2005, 4:463-485.
37. Lawton MP, Van Haitsma K, Perkinson M, Ruckdeschel K. Observed affect and quality of life in dementia: Further affirmations and problems. J Ment Health Aging 1999, 5:69-81.
38. Snyder M, Ryden MB, Shaver P, Wang J, Savik K, Gross CR, et al. The Apparent Emotion Rating Instrument: assessing affect in cognitively impaired elders. Clin Gerontol 1998, 18:17-29.
39. Stevenson KM, Brown RL, Dahl JL, Ward SE, Brown MS. The discomfort behavior scale: a measure of discomfort in the cognitively impaired based on the minimum data set 2.0. Res Nurs Health 2006, 29:576-587.
40. Hurley AC, Volicer BJ, Hanrahan PA, Houde S, Volicer L. Assessment of discomfort in advanced Alzheimer patients. Res Nurs Health 1992, 15:369-377.

Additional file 5: Summary of measure details, methods of administration, and feasibility and applicability in care

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
Pain						
APS [**1**, 2, 3]	6 items	Each item rated from 0 (absent) to 3 (severe) Range 0-18 higher score indicating more severe pain	**Observation** [**1,** 3] Observation at rest and observation of standardized exercise program [2] of: Pain signs: Vocalisation Facial expression Change in body language Behavioral change Physiological change Physical changes	**Observation period** [**1**, 3] Observation at rest (5 minutes) and observation of standardized exercise program (20-30 minutes) [2]	1 minute [1]	None specified by measure developer Training provided on correct use of measure, rater training continued throughout data collection period [2]
CNPI [3, **4**, 5, 6]	6 items	Each item is dichotomously scored as present or absent under 2 conditions. Range of subscores 0-6 Range of summed total score 0-12 higher score reflecting more pain signs	**Observation during rest and movement** [3, **4**] Video recording of a resident at rest and during activity [5] Video recording at baseline (at rest), control (swabbing), vaccination and movement-induced pain [6] of: Pain signs: Nonverbal vocalisations Facial grimacing/ wincing Bracing Rubbing Restlessness Vocal complaints	**Observation period** [3, **4**] 1 minute observation at rest and series of care activities [5] Baseline observation (3-5 minutes), swabbing, vaccination and movement-induced pain [6]	Less than 5 minutes [6]	None specified by measure developer

Name of Measure[a]	**Number of items**	**Scoring**	**Method of administration[a, b]**	**Rating period[a, b]**	**Time to administer[a]**	**Training required[a]**
CPAT **[7]**	5 items	Each item dichotomously scored as present or absent Range of summed total scores 0-5 with higher score indicating more pain signs	**Observation of pain signs:** Facial expression Behavior Mood Body language Activity level	**Observation period of 1 minute**	**1 minute**	**45 minutes training provided to Certified Nursing Assistants**
Doloplus-2 [3]	10 items	Each item rated from 0-3 Total score range 0-30 higher score indicating increased pain	Observation Pain signs: 5 somatic reactions 2 psychomotor reactions 3 psychosocial reactions	Observation in different situations that could result in pain therefore not pain at specific moment in time	No information	Nurse participants received training from project team
MPS **[8]**	8 items	Each item rated from 0-3 Range 0-24 higher scores reflect more pain signs	**Observations with light touch, or observation during rest or activity** Pain signs: Facial expression Breathing Vocalization Body language Agitation Appetite/ sleep Physical state	**Up to 5- minute observation or during personal care provision**	No information	**Participating nurses received 2 hour training on MPS and study procedures**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
NOPPAIN [6, 9]	9 care conditions 6 pain responses: presence and intensity 1 overall pain intensity	Each 6 pain responses rated dichotomously as present or absent Likert scale of pain intensity for each pain response Overall pain intensity (no pain, little pain, moderate pain, quite bad pain, very bad pain, pain is almost unbearable)	Video recording at baseline (at rest), control (swabbing), vaccination and movement-induced pain [6] Video recording of activity-based protocol to elicit pain behaviors: participants asked to sit, stand, lie on a bed, walk in place, and transfer between activities for 1 minute intervals for a total of 10 minutes [9] Pain signs: Pain words Pain noises Pain faces Rubbing Bracing Restlessness	Baseline observation (3-5 minutes), swabbing, vaccination and movement-induced pain [6] Participants asked to sit, stand, lie on a bed, walk in place, and transfer between activities for 1 minute intervals for a total of 10 minutes [9]	Less than five minutes [6]	Designed to require minimal training Raters completed brief standardized CD training program developed by measure developer [9]

Name of measure[a]	**Number of items**	**Scoring**	**Method of administration[a, b]**	**Rating period[a, b]**	**Time to administer[a]**	**Training required[a]**
PAINAD [2, 5, 6, **10**, 11]	5 items	Each item rated from 0-2 Range 0-10 higher score reflects more severe pain	Observation at rest and observation of standardized exercise program [2] Video recording of a resident at rest and during activity [5] Video recording at baseline (at rest), control (swabbing), vaccination and movement-induced pain [6] **Observations during rest, pleasant activity and caregiving activity [10]** Observations of period of likely pain (transfer) and unlikely pain [11] Pain signs: Breathing Negative vocalisation Facial expression Body language Consolability	Observation at rest (5 minutes) and observation of standardized exercise program (20-30 minutes) [2] 1 minute observation at rest and series of care activities [5] Baseline observation (3-5 minutes), swabbing, vaccination and movement-induced pain [6] **5 minute observation for each activity type [10]** 5 minute observation for each period [11]	Less than 5 minutes [6]	Training provided on correct use of the measure, rater training continued throughout the data collection period [2] Training session on measures and video scoring [5] **2-hour training developed by measure developer [10]**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
PACSLAC [2, 6, **12**, 13, 14]	60 items	Dichotomous (present/ absent) for each item Range 0-60 higher score reflect more pain signs	Observation at rest and observation of standardized exercise program [2] Video recording at baseline (at rest), control (swabbing), vaccination and movement-induced pain [6] **Completed from memory thinking about 2 pain events, non-pain distressing event, and time when a resident was calm [12]** Observations while providing personal care [13] Observation during period of rest and period of activity (naturally occurring pain) [14] Pain signs: Facial expressions Activity/ body movement Social/ personality/ mood indicators Physiological indicators/ Eating and sleeping changes/ Vocal behaviors	Observation at rest (5 minutes) and observation of standardized exercise program (20-30 minutes) [2] Baseline observation (3-5 minutes), swabbing, vaccination and movement-induced pain [6] **Completed based on knowledge of and memory of residents [12]** Following personal care provision [13] Following observation of rest and activity [14]	5 minutes [6, **12**, 13]	**None specified by measure developer [12]** Training provided on correct use of measure, rater training continued throughout data collection period [2] Completed by caregiver staff who were provided by 1-hour training by community psychogeriatric nurse and medical undergraduate researcher [13] Five minute video training provided to research assistants on pain behaviors and pain interview with resident [14]

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
PACSLAC-II **[15]**	31 items	Dichotomous (present/ absent) for each item Range of 0-31 higher score reflecting more pain	**Video recording at baseline (at rest), control (swabbing), vaccination and movement-induced pain by trained research assistant** **Observations while providing personal care by long-term care staff** Pain signs: Facial expressions Verbalizations and vocalizations Body movements Changes in interpersonal interactions Changes in activity patterns or routines Mental status changes	**Baseline observation (3-5 minutes), swabbing, vaccination and movement-induced pain**	**Not specified**	**Instructions provided to long-term care staff**
PACI [14, 16, 17]	7 items	Dichotomous yes/ no response Range of 0-7 higher score reflects increased pain	Observation during period of rest and period of activity (naturally occurring pain) [14] Observation movement-exacerbated painful event occurring in care [16] Video recording of 2 potentially painful situations: physiotherapy and personal care [17] Pain signs: Facial expression Vocal Body movements	Following observation of rest and activity [14] 2 minute interval [16] Observation of personal care and physiotherapy situations [17]	10 seconds to rate following observation [17]	Five minute video training provided to research assistants on pain behaviors and pain interview with resident [14] Study investigator and research assistant trained to use measure through five minute video of pain behaviors [16] Brief training video of pain behaviors [17]

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
PADE [6, **18**]	24 items	Items 1-12, 14, 22-24 are rated using a Likert scale (1-4) Items 13, 15-21 are rated using a multiple choice score (1-4) Part I: higher score reflects higher distress Part III: greater dependence	Video recording at baseline (at rest), control (swabbing), vaccination and movement-induced pain [6] **Observation of behaviour [18]** Part I: Physical (observable facial expression, breathing pattern and posture), Part II: global assessment of pain Part III: functional abilities	Baseline observation (3-5 minutes), swabbing, vaccination and movement-induced pain [6] **5 minute observation [18]**	Less than 5 minutes [6] **With practice: 5-10 minutes [18]**	**Completed by trained care staff with 1-hour training by investigators [18]**
PBOICIE **[19]**	10 items	Each item rated with dichotomous response (yes/no) with range of 0-10	**Person with dementia is rated during administration of activity protocol** Pain signs: Distorted ambulation or gesture Audible expression of distress Facial/ non-audible expression of distress Changes in daily routine	**Duration of activity protocol**	**No information**	**Completed by trained RA by first author Guidelines developed for coding each behaviour**
Oral health signs and symptoms						
BOHSE **[20]**	10 items	Each item has 3 descriptors Rated on 3-point scale (0-2) Range 0-20 higher score reflects less healthy oral health	**Examined BOHSE as a guide, sitting on bed or in chair**	**Examination period**	**Mean: 5.6 minutes (range 5-20)**	**Completed by nursing home staff of all grades. Two 2-hour in-service training provided with oral anatomy, common dental diseases, instruments, scoring, observed and supervised examination**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
OHAT **[21]**	8 items	Rated on 3-point scale (0-2) Range 0-16 higher score less healthy oral health	**Observation and examination**	**Examination period**	**Mean: 7.9 minutes (range 1-30)**	**Three hour training and calibration**
Neuropsychiatric symptoms						
NPI-Q **[22]**	Each of the 12 symptoms is assessed with 1 screening question	Screening question: yes/no If yes, symptom severity is scored on 3-point scale 1 (mild) to 3 (severe), range 0-36 with higher score reflecting higher symptom burden	**Modified from original NPI from interview to 2-page self-administered questionnaire with written instructions. Anchor points are provided for symptom severity. Symptom severity only (not symptom frequency) is assessed**	**Last 4 weeks**	**5 minutes or less**	**Completed by unpaid caregivers with written instructions and anchor points. No training provided**
CDBQ **[23]**	2 parts relating to person with dementia: a) 62 b) 19	a) Frequency from 'never' to 'constantly' b) Severity from 'not present' to 'severe'	**Completed by caregiver based on observations**	**Symptom present in last six months, if present, scored over last month**	**No information**	**Unpaid caregivers completed without training**
Depression						
BDI-modified **[24]**	21	Multiple choice responses to each item with a maximum score of 63 higher score reflecting worse depression	**Original scale modified to be completed by caregiver proxies, modifications consisted of simple word changes**	**Last 2 weeks**	**No information**	**Unpaid caregivers completed without training**
CESD–modified **[24]**	20	All items rated on a 4-point scale (0-3) frequency with range from 0-60 higher scores reflecting higher depression	**Original scale modified to be completed by caregiver proxies, modifications consisted of simple word changes**	**Last 2 weeks**	**No information**	**Unpaid caregivers completed without training**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
CSDD–modified **[25]**	19	All items rated on a 3-point scale (0-2) with range 0-38 higher score reflects worse depression	**Original scale modified to be completed by proxy based on nursing observations, nurse-patient interactions, handovers, notes and informal discussions** Mood-related signs: Behavioral disturbance Physical signs Cyclic functions Ideational disturbance	**Last 1-2 weeks**	**No information**	**Completed by geriatric psychiatry ward nursing staff who were provided with instruction and access to instruction manual**
CSDD-M-LTCS **[26]**	19	CSDD-M-LTCS severity ratings were modified to frequency ratings	**CSDD-M-LTCS modified based on cognitive testing to support use by non-clinicians** Mood-related signs: Behavioral disturbance Physical signs Cyclic functions Ideational disturbance	**Last week**	**No information**	**Instructions with a scoring algorithm. Training provided to long-term care staff (30 minutes)**
DDMS - modified **[25]**	17	All items rated on a 7-point scale (0-6) with range of 0-17	**Original scale modified to be completed by proxy based on nursing observations, nurse-patient interactions, handovers, notes and informal discussions**	**Last 1-2 weeks**	**No information**	**Completed by geriatric psychiatry ward nursing staff who were provided with instruction and access to instruction manual**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
DSS - modified **[25]**	9	8 items rated 0-2,1 item rated 0-1 Range 0-17	**Original scale modified to be completed by proxy based on nursing observations, nurse-patient interactions, handovers, notes and informal discussions**	**Last 1-2 weeks**	**No information**	**Completed by geriatric psychiatry ward nursing staff who were provided with instruction and access to instruction manual**
GDS - Collateral source/ informant version [**24, 27**, 28]	15-item 30-item	Yes/no response Range 0-15 or 0-30 depending on version used with higher score indicating worse depression	**Original scale modified through simple changes to wording to be self-completed by proxy based on knowledge of person [24]** **Original scale modified to be self-completed by proxy based on knowledge of person [27,** 28]	**Last 2 weeks [24]** **Last week [27,** 28]	**No information**	**Completed by unpaid caregiver or nursing home caregiver staff without training**
Hayes and Lohse Non-verbal Depression Scale **[29]**	20	0 (almost never) to 4 (always) Range 0-80 with higher scores indicating worse depression	**Observation of person with dementia**	**Last month**	**No information**	**Completed by staff who know resident well including registered nurses, social workers or any other professional staff. No details of training provided**
MDSDRS **[30**, 31, 32, 33]	7	0 (not at all)-2 (daily or almost daily) Range 0-14 with higher scores indicating worse depressions	**Informal discussion with resident, observe signs, discussions with staff and family, clinical record [30**, 31, 32, 33]	**Last 30 days [30**, 31, 32, 33]	No information	MDS-trained nurses

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
Anxiety						
GAI-modified **[34]**	20	Dichotomous (agree/disagree) 0-20 with higher score reflecting worse anxiety	**Normally administered to person with dementia, in this study modified for self-completion by proxy, based on knowledge of the person with dementia**	**Last week**	**No information**	**Completed by unpaid caregiver without training**
PSWQ-A-modified **[34]**	8	1-5 with total range from 8-40 higher scores reflecting worse anxiety	**Normally administered to person with dementia, in this study modified for self-completion by proxy, based on knowledge of the person with dementia**	**No information**	**No information**	**Completed by unpaid caregiver without training**
Psychological wellbeing						
PGCARS [35]	6	Scored according time behaviour evidenced Never <16 seconds 16-59 seconds 1-5 minutes >5 minutes	20 minute video recording of residents over period of 12 days at times of high agitation or passivity Administered based on observed behaviour: Pleasure Anger Anxiety Depression Interest Contentment	20 minutes	No information	Research assistants and video raters provided with 2-day training
PWB-CIP **[36]**	11	Higher scores reflect higher wellbeing	**Administered based on observed behavior**	**Last 24 hours**	**5-10 minutes**	**Completed by primary unpaid caregiver without training**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
AARS **[37]**	5	Scored according time behaviour evidenced Never <16 seconds 16-59 seconds 1-2 minutes >2 minutes	**Administered based on observed behaviour. Descriptions of signs or indicators of each emotion are provided** **Pleasure** **Anger** **Anxiety/Fear** **Depression/Sadness** **Interest**	**5 minute period although other time periods can be specified**	**No information**	**Training to certified nursing assistants: Group and one-to-one teaching sessions with supervised practice**
AER **[38]**	6	Dichotomous (present/absence) for any affective state for which indicators are observed 15 points assigned for every positive state marked 1; and 15 points for every negative state marked 0 Total score range from 0 90 higher score reflecting positive state	**Observer-rated using verbal and no-verbal indicators. Rater observes resident and circles indicators observed in this time for each of the emotions. Prior information of the resident is not considered**	**5-10 minutes**	**No information**	**Training to research assistants: 2 hours including interpretation of indicators and supervised practice**
Discomfort						
DBS **[39]**	17 items	Each item rated 0-6, with range of 0-102	**Rated as part of MDS based on medical record, observations, interactions with resident, family, care staff, physician**	**Past week**	**No information**	**MDS-trained nurses**

Name of measure[a]	Number of items	Scoring	Method of administration[a, b]	Rating period[a, b]	Time to administer[a]	Training required[a]
DS-DAT [2, **40**]	9 items	Frequency, intensity, and duration of each of the 9 categories is scored Range: 0-27 with higher score reflecting increased discomfort	**Observed in natural setting without stimuli [40]** Observation at rest and observation of standardized exercise program [2] Observation of 9 behavioral indicators: Noisy breathing Negative vocalisation Content facial expression Frightened facial expression Frown Relaxed body language Fidgeting	**5 minute observation [40]** Observation at rest (5 minutes) and observation of standardized exercise program (20-30 minutes) [2]	No information	Training provided on correct use of measure, rater training continued throughout data collection period [2] **Training developed, but not detailed [40]**

[a]Text and references in bold indicate data reported in the original validation study of the reported version of the measure

[b]Where details of methods of administration are not reported in studies, they are reported as following original administration methods

APS: Abbey Pain Scale, CNPI: Checklist of Nonverbal Behaviors, CPAT: CNA Pain Assessment Tool, MPS: Mahoney Pain Assessment Tool, NOPPAIN: Non-communicative Patient's Pain Assessment Instrument, PAINAD: Pain Assessment in Advanced Dementia, PACSLAC: Pain Assessment Checklist for Seniors with Limited Ability to Communicate, PACI: Pain Assessment in Communicatively Impaired, PADE: Pain Assessment for Dementing Elderly, PBOICIE: Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders, BOHSE: Brief Oral Health Status Examination, OHAT: Oral Health Assessment Tool, NPI-Q: Neuropsychiatric Inventory Questionnaire, CDBQ: California Dementia Behavior Questionnaire, BDI-modified: Beck Depression Inventory – modified, CESD-Modified: Center for Epidemiologic Studies Depression Scale – modified, CSDD-modified: Cornell Scale for Depression in Dementia, CSDD-M-LTCS: Cornell Scale for Depression in Dementia Modified for use by Long Term Care Staff, DDMS-modified: Depression in Dementia Mood Scale – modified, DSS-modified: Depression Signs Scale – modified, GDS: Geriatric Depression Scale, MDSDRS: Minimum Data Set Depression Rating Scale, GAI – modified: Geriatric Anxiety Inventory – modified, PSWQ-A-modified: Penn State Worry Questionnaire – Abbreviated – modified, PGCARS: Philadelphia Geriatric Center Affect Rating Scale, PWB-CIP: Psychological Wellbeing in Cognitively Impaired Persons, AARS: Apparent Affect Rating Scale, AER: Apparent Emotion Rating Instrument, DBS: Discomfort Behavior Scale, DS-DAT: Discomfort Scale for patients with Dementia of Alzheimer's Type

CD: Compact disc

References:

1. Abbey J, Piller N, De Bellis A, Esterman A, Parker D, Giles L, et al. The Abbey pain scale: a 1-minute numerical indicator for people with end-stage dementia. Int J Palliat Nurs 2004, 10:6-13.
2. Liu JYW, Briggs M, Closs SJ. The psychometric qualities of four observational pain tools (OPTs) for the assessment of pain in elderly people with osteoarthritic pain. J Pain Symptom Manage 2010, 40:582-598.
3. Neville C, Ostini R. A psychometric evaluation of three pain rating scales for people with moderate to severe dementia. Pain Manag Nurs 2014, 15:798-806.
4. Feldt KS. The Checklist of Nonverbal Pain Indicators (CNPI). Pain Manag Nurs 2000, 1:13-21.
5. Ersek M, Herr K, Neradilek MB, Buck HG, Black B. Comparing the psychometric properties of the checklist of nonverbal pain behaviors (CNPI) and the pain assessment in advanced dementia (PAIN-AD) instruments. Pain Med 2010, 11:395-404.
6. Lints-Martindale AC, Hadjistavropoulos T, Lix LM, Thorpe L. A comparative investigation of observational pain assessment tools for older adults with dementia. Clin J Pain 2012, 28:226-237.
7. Cervo FA, Bruckenthal P, Chen JJ, Bright-Long LE, Fields S, Zhang G, et al. Pain assessment in nursing home residents with dementia: psychometric properties and clinical utility of the CNA Pain Assessment Tool (CPAT). J Am Med Dir Assoc 2009, 10:505-510.
8. Mahoney AEJ, Peters L. The Mahoney pain scale: Examining pain and agitation in advanced dementia. Am J Alzheimers Dis Other Demen 2008, 23:250-261.
9. Horgas AL, Nichols AL, Schapson CA, Vietes K. Assessing pain in persons with dementia: relationships among the non-communicative patient's pain assessment instrument, self-report, and behavioral observations. Pain Manag Nurs 2007, 8:77-85.
10. Warden V, Hurley AC, Volicer L. Development and Psychometric Evaluation of the Pain Assessment in Advanced Dementia (PAINAD) Scale. J Am Med Dir Assoc 2003, 4:9-15.
11. DeWaters T, Faut-Callahan M, McCann JJ, Paice JA, Fogg L, Hollinger-Smith L, et al. Comparison of self-reported pain and the PAINAD scale in hospitalized cognitively impaired and intact older adults after hip fracture surgery. Orthop Nurs 2008, 27:21-28.

12. Fuchs-Lacelle S, Hadjistavropoulos T. Development and preliminary validation of the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC). Pain Manag Nurs 2004, 5:37-49.
13. Cheung G, Choi P. The use of the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) by caregivers in dementia care facilities. N Z Med J 2008, 121:21-29.
14. Kaasalainen S, Akhtar-Danesh N, Hadjistavropoulos T, Zwakhalen S, Verreault R. A comparison between behavioral and verbal report pain assessment tools for use with residents in long term care. Pain Manag Nurs 2013, 14:e106-e114.
15. Chan S, Hadjistavropoulos T, Williams J, Lints-Martindale A. Evidence-based development and initial validation of the pain assessment checklist for seniors with limited ability to communicate-II (PACSLAC-II). Clin J Pain 2014, 30:816-824.
16. Kaasalainen S, Crook J. A comparison of pain-assessment tools for use with elderly long-term-care residents. Can J Nurs Res 2003, 35:58-71.
17. Kaasalainen S, Stewart N, Middleton J, Knezacek S, Hartley T, Ife C, et al. Development and evaluation of the Pain Assessment in the Communicatively Impaired (PACI) tool: part II. Int J Palliat Nurs 2011, 17:431-438.
18. Villanueva MR, Smith TL, Erickson JS, Lee AC, Singer CM. Pain Assessment for the Dementing Elderly (PADE): reliability and validity of a new measure. J Am Med Dir Assoc 2003, 4:1-8.
19. Tsai PF, Beck C, Richards KC, Phillips L, Roberson PK, Evans J. The Pain Behaviors for Osteoarthritis Instrument for Cognitively Impaired Elders (PBOICIE). Res Gerontol Nurs 2008, 1:116-122.
20. Kayser-Jones J, Bird WF, Paul SM, Long L, Schell ES. An instrument to assess the oral health status of nursing home residents. Gerontologist 1995, 35:814-824.
21. Chalmers JM, King PL, Spencer AJ, Wright FAC, Carter KD. The oral health assessment tool--validity and reliability. Aust Dent J 2005, 50:191-199.
22. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. J Neuropsychiatry Clin Neurosci 2000, 12:233-239.

23. Victoroff J, Nielson K, Mungas D. Caregiver and clinician assessment of behavioral disturbances: the California Dementia Behavior Questionnaire. Int Psychogeriatr 1997, 9:155-174.
24. Logsdon RG, Teri L. Depression in Alzheimer's disease patients: Caregivers as surrogate reporters. J Am Geriatr Soc 1995, 43:150-155.
25. Elanchenny N, Shah A. Evaluation of three nurse-administered depression rating scales on acute admission and continuing care geriatric psychiatry wards. Int J Methods Psychiatr Res 2001, 10:43-51.
26. Watson LC, Zimmerman S, Cohen LW, Dominik R. Practical depression screening in residential care/assisted living: five methods compared with gold standard diagnoses. Am J Geriatr Psychiatry 2009, 17:556-564.
27. Nitcher RL, Burke WJ, Roccaforte WH, Wengel SP. A collateral source version of the Geriatric Depression Rating Scale. Am J Geriatr Psychiatry 1993, 1:143-152.
28. Li Z, Jeon YH, Low LF, Chenoweth L, O'Connor DW, Beattie E, et al. Validity of the geriatric depression scale and the collateral source version of the geriatric depression scale in nursing homes. Int Psychogeriatr 2015, 27:1495-1504.
29. Hayes PM, Lohse D, Bernstein I. The development and testing of the Hayes and Lohse Non-Verbal Depression Scale. Clin Gerontol 1991, 10:3-13.
30. Burrows AB, Morris JN, Simon SE, Hirdes JP, Phillips C. Development of a Minimum Data Set-based depression rating scale for use in nursing homes. Age Ageing 2000, 29:165-172.
31. Anderson RL, Buckwalter KC, Buchanan RJ, Maas ML, Imhof SL. Validity and reliability of the Minimun Data Set Depression Rating Scale (MDSDRS) for older adults in nursing homes. Age Ageing 2003, 32:435-438.
32. Koehler M, Rabinowitz T, Hirdes J, Stones M, Carpenter GI, Fries BE, et al. Measuring depression in nursing home residents with the MDS and GDS: An observational psychometric study. BMC Geriatr 2005, 5:1471-2318.
33. Martin L, Poss JW, Hirdes JP, Jones RN, Stones MJ, Fries BE. Predictors of a new depression diagnosis among older adults admitted to complex continuing care: Implications for the depression rating scale (DRS). Age Ageing 2008, 37:51-56.

34. Bradford A, Brenes GA, Robinson RA, Wilson N, Snow AL, Kunik ME, et al. Concordance of self- and proxy-rated worry and anxiety symptoms in older adults with dementia. J Anxiety Disord 2013, 27:125-130.

35. Kolanowski A, Hoffman L, Hofer SM. Concordance of self-report and informant assessment of emotional well-being in nursing home residents with dementia. J Gerontol 2007, 62:20-27.

36. Burgener SC, Twigg P, Popovich A. Measuring psychological well-being in cognitively impaired persons. Dementia 2005, 4:463-485.

37. Lawton MP, Van Haitsma K, Perkinson M, Ruckdeschel K. Observed affect and quality of life in dementia: Further affirmations and problems. J Ment Health Aging 1999, 5:69-81.

38. Snyder M, Ryden MB, Shaver P, Wang J, Savik K, Gross CR, et al. The Apparent Emotion Rating Instrument: assessing affect in cognitively impaired elders. Clin Gerontol 1998, 18:17-29.

39. Stevenson KM, Brown RL, Dahl JL, Ward SE, Brown MS. The discomfort behavior scale: a measure of discomfort in the cognitively impaired based on the minimum data set 2.0. Res Nurs Health 2006, 29:576-587.

40. Hurley AC, Volicer BJ, Hanrahan PA, Houde S, Volicer L. Assessment of discomfort in advanced Alzheimer patients. Res Nurs Health 1992, 15:369-377.

2.1 Summary of key points and gaps

This systematic review found that there are no comprehensive assessment measures developed specifically for care home staff without a clinical qualification to assess physical symptoms and emotional, social and existential concerns for people who have difficulty expressing their wishes and concerns due to dementia. It is proposed that such a measure could address an important gap in the care of people with dementia living in care homes through facilitating prompt detection and management of potentially distressing symptoms and concerns, and in turn, reducing avoidable distress and improving quality of life.

3. Identification of a comprehensive measure to develop as an intervention for use in routine care of people with dementia in care homes

3.1 Introduction

This chapter starts by discussing the benefits of adapting an existing comprehensive measure versus developing a completely new measure. Having presented the argument for adapting an existing measure, a review of measures used in palliative care is conducted to identify potentially suitable measures and compare their relative strengths and limitations of adapting for this purpose and population. A rationale is provided for the selected measure, and the chapter concludes with a brief summary of this measure, and next steps on how to adapt it to use in routine practice for people with dementia in care homes.

3.2 Developing a new measure or adapting an existing measure?

A decision needed to be taken as to whether to develop a new measure or adapt an existing one. The systematic review [chapter 2: publication 1] identified 32 measures to assess individual symptoms or groups of symptoms. In addition, there is a plethora of measures developed for research and/or clinical care for people with dementia including those that measure quality of life (107-110), functional ability (111-113), and behaviours that challenge (114-120). Results of a pan-European survey of measures used in palliative and advanced disease care found that respondents used 116 measurement tools in clinical care and audit, and that 99 of these were cited less than 10 times (84). Based on the results of this survey, the authors recommended that the number of tools be rationalised, and that new measurement tools are not developed but rather existing ones refined (84). The decision was therefore taken to identify a comprehensive measure of symptoms and concerns with robust psychometric properties, and established for use in routine clinical care, to adapt for use as an intervention in the routine care of people with dementia in care homes by care home staff.

3.3 Selecting an existing measure to adapt for people with dementia

No comprehensive measure developed for care home staff to use as an intervention as part of routine care was identified from the literature [Chapter 2: Publication 1]. Palliative care, with its aim to provide comprehensive assessment of all physical symptoms and emotional, social and existential concerns experienced by people with life-threatening and chronic illness, and their families (14, 101), is advocated for people with dementia (22). An established palliative care measure developed for use in routine clinical care is therefore well-suited for adaptation for this population and purpose.

As part of the PhD preparation, a scoping review on measures used in palliative care for people with dementia was conducted (see Appendix A for methods). This initial scoping review identified four reviews/evaluations of measures, all published in the previous two years. These included a systematic review of measures used to assess the quality of palliative care provided in care home settings (121), and a series of studies to identify palliative and end of life measures used in care home settings and evaluate their properties (104, 122, 123). The identified measures from these reviews and evaluations were appraised to identify the most suited measure for adaptation, rather than repeating or updating a systematic review.

3.3.1 Aim

To identify the most suitable comprehensive measure for adaptation to support assessment and management of physical symptoms and emotional, social and existential concerns by care home staff without a clinical qualification for people with dementia living in care homes who may have difficulty in verbally expressing their wishes and concerns.

3.3.2 Methods

3.3.2.1 Study design

This was a review of reviews/evaluations of measures for people with dementia living in care homes identified in the scoping review (Appendix A). The identified reviews/evaluations are detailed above and reported in more detail below. The identification and appraisal of suitable measures included in the reviews/evaluations incorporated two stages. In stage one, all measures identified from the reviews and evaluations were examined against eligibility criteria informed by

the theoretical model and measurement properties detailed in chapter one. Those measures not meeting the eligibility criteria were excluded. In stage two, the remaining measures were examined in greater detail, and their relative strengths and weaknesses for adaptation were compared and contrasted. Reference list searches of the four reviews/evaluations was conducted to identify relevant papers cited. Publications were included if in English, reporting a review or original study on the psychometric properties, acceptability and feasibility for use in care homes, and/or translations or cross-cultural validations of any of the measures meeting the stage one eligibility. Conference abstracts and grey literature were excluded.

3.3.2.2 Eligibility criteria for measures

The theoretical model and measurement properties detailed in chapter one were utilised to develop a set of criteria to examine each of the identified measures.

Stage one eligibility:

(i) Measures that are **proxy-reported** rather than patient-reported. As the measure is developed to support assessment of people who may have challenges expressing their wishes and concerns, patient-reported measures were excluded from consideration.

(ii) The aim of the measure i.e. what the measure was developed to assess. Measures that aimed to assess predominantly quality of care, quality of life, single symptoms or single care processes e.g. communication did not meet the criteria for adaptation and were excluded from consideration.

(iii) Whether the measure was developed to be used pre-death. Measures developed for administering post-death to evaluate quality of dying were excluded as the measure is required to **inform care prospectively** and be **relevant** for all people with dementia in care homes not just those at the dying phase. However, those measures that had been developed for post-death but had also been used or evaluated before death and may therefore have some relevance pre-death, were included for consideration as a potential measure for adaptation.

(iv) Whether the measure had been undergone psychometric evaluation in people with dementia in care homes. Those measures that had not undergone psychometric

evaluation in this population were excluded to ensure that only measures with some evidence of **validity and reliability** in this population were included for consideration.

Stage two eligibility:

(i) Whether the measure was developed to assess comprehensive symptoms and concerns. Those that were developed to assess comprehensive symptoms and concerns experienced by people with dementia throughout the disease trajectory were considered preferable so as to maximise **relevance** and therefore **content validity** and **acceptability** to all people with dementia living in care homes (124).

(ii) Evidence on how well-established it is as a clinical assessment measure, including ease-of-use of the measure and any training to inform whether it is **acceptable and feasible** for routine care.

(iii) Whether the measure requires a clinical qualification to complete it. Those measures explicitly stating that they were developed or tested when used by health care professionals with a clinical qualification were considered to require a clinical qualification to administer. This informed **acceptability** and **comprehension** for proxies without a clinical qualification.

(iv) A detailed review of the psychometric properties of the measure in people with dementia in care homes to determine **validity, reliability, responsiveness** and **interpretability.**

(v) Evidence on how well-established and **available** the measure is, including translations, cross-cultural validations, evidence of use in routine clinical care and any data on access and charges.

3.3.2.3 Data extraction

Stage one data extraction:

Data extraction of the reviews/evaluations included name of lead author, date and country of publication, the aim of the study, study design, and inclusion criteria of measures. Data extracted on the measures included name of the measure, date of publication, country it was developed in, whether the measure self-reported or proxy-reported, what the measure aimed to assess, when the measure was designed to be completed i.e. pre-death or post-death, whether the measure had been psychometrically evaluated in people with dementia living in care homes, whether the

measure had been specifically developed for people with dementia, and if so, which stages of dementia, and whether it had been developed for people living in care homes.

Stage two data extraction:

Data extraction in stage two was from the four reviews/evaluations and additional identified studies from the reference list searches. Data extracted included the measure items, the methods of psychometric evaluation, the psychometric properties of the measures, methods of assessment of feasibility and acceptability, and feasibility and acceptability data. In addition, any data reporting how established and accessible the measure and any training is, and data on translations and cross-cultural validations. Both qualitative and quantitative data were extracted.

3.3.2.4 Assessment of quality and data synthesis

Methods and quality of psychometric testing was assessed using established quality criteria (106). Data on the psychometric properties, acceptability and feasibility of the measures used in routine care were compared and contrasted for each measure to determine the relative strengths and weakness of adaptation.

3.3.3 Results

The four reviews/evaluations included a systematic review of measures of quality of palliative care for use in care home settings to identify and assess the psychometric properties and feasibility of measures used to assess the quality of care in palliative care (121), a literature search and qualitative content analysis (123), psychometric evaluation (122), and comparison of the psychometric properties and feasibility (104) of measures to assess the quality of care and quality of dying for people living in care homes, including those with dementia or cognitive impairment. Table 2 provides details on the four reviews and the measures identified in each.

Table 2 Study details of reviews of measures used in care homes for people with dementia

Lead author, date of publication, country	**Aim of review**	**Study design**	**Inclusion criteria**	**Measures identified/evaluated**
Parker, 2011, Australia (121)	To identify and assess the psychometric properties and feasibility of measures used to assess the quality of palliative care in care homes	Systematic review	Psychometric evaluations of measures suitable for use in care homes	EOLD-CAD (125) EOLD-SM (125) EOLD-SWC (125) FATE (126) FPCS (127) POS (87) QODD (128) QOD-LTC (129) QOD-LTC-C (129) QOLC-E (130) mQOLC-E (131) TIME (132) RAI-PC (133)
van Soest-Poortvliet, 2011, the Netherlands (123)	To evaluate the content of measures to assess the quality of care and quality of dying for residents dying in care homes	Literature search and qualitative content analysis of measures	Measures were included if: - Used to assess quality of dying and/or care when dying - Used in care home settings - Developed, validated or widely used in populations that include people with dementia or cognitive impairment - Possible to calculate (sub)scale scores	EOLD-CAD (125) EOLD-SM (125) EOLD-SWC (125) FATE-S (134) FPCS (127) FPPFC (135) MSSE (136) POS (87) QOD-LTC (129) TIME (132) RAI-PC (133)
van Soest-Poortvliet, 2012, the Netherlands (122)	To assess and compare the validity and reliability of measures of perceived quality of care and quality of dying for residents dying with dementia in care homes	Psychometric evaluation of measures identified in van Soest-Poortvliet et al (2011) (123)	Measures were included if: - Used to assess quality of dying and/or care when dying - Used in care home settings - Developed, validated or widely used in populations that include people with dementia or cognitive impairment - Possible to calculate (sub)scale scores	EOLD-CAD (125) EOLD-SM (125) EOLD-SWC (125) FATE-S (134) FPCS (127) FPPFC (135) MSSE (136) POS (87) QOD-LTC (129) TIME (132)
van Soest-Poortvliet, 2012, the Netherlands and US (104)	To compare measures to assess quality of care and quality of dying for people with and without dementia dying in care homes, and provide an overview of feasibility, validity and reliability in the Netherlands and US	Post-death interviews and questionnaires to family and professional carers of people who died with dementia in the Netherlands and with and without dementia in the US (122, 123, 137) of measures identified in van Soest-Poortvliet et al (2011) (123)	Measures were included if: - Used to assess quality of dying and/or care when dying - Used in care home settings - Developed, validated or widely used in populations that include people with dementia or cognitive impairment - Possible to calculate (sub)scale scores	EOLD-CAD (125) EOLD-SM (125) EOLD-SWC (125) FATE-S (134) FPCS (127) FPPFC (135) MSSE (136) POS (87) QOD-LTC (129) TIME (132)

EOLD: End of Life in Dementia; EOLD-SM: Symptom Management; EOLD-SWC: Satisfaction With Care; EOLD-CAD: Comfort Assessment in Dying; FATE: Family Assessment of Treatment at the End of life; FATE-S: Family Assessment of Treatment at the End of life - Short version; FPCS: Family Perceptions of Care Scale; FPPFC: Family Perceptions of Physician-Family caregiver Communication; MSSE: Mini Suffering State Examination; POS: Palliative care Outcome Scale; QODD: Quality of Dying and Death; QOD-LTC: Quality of Dying in Long Term Care; QOD-LTC-C: Quality of Dying in Long Term Care – Cognitively intact; QOLC-E: Quality Of Life Concerns in End of life questionnaire; mQOLC-E: modified Quality Of Life Concerns in End of life questionnaire; RAI-PC: Resident Assessment Instrument for Palliative Care; TIME: Toolkit of Instruments to Measure End of life care, US: United States

Sixteen measures were identified from the reviews: End of Life in Dementia – Comfort Assessment in Dying (EOLD-CAD) (125), End of Life in Dementia – Symptom Management (EOLD-SM) (125), End of Life in Dementia – Satisfaction with Care (EOLD-SWC) (125), Family Assessment of Treatment at the End of life (FATE) (126), Family Assessment of Treatment at the End of life –Short version (FATE-S) (134), Family Perceptions of Care Scale (FPCS) (127), Family Perceptions of Physician-Family caregiver Communication (FPPFC) (135), Mini Suffering State Examination (MSSE) (136), Palliative care Outcome Scale (POS) (87), Quality of Dying and Death (QODD) (128), Quality of Dying in Long Term Care (QOD-LTC) (129), Quality of Dying in Long Term Care – Cognitively Intact (QOD-LTC-C) (129), Quality of Life Concerns in End of life questionnaire (QOLC-E) (130), modified Quality of Life Concerns in End of life questionnaire (mQOLC-E) (131), Resident Assessment Instrument for Palliative Care (RAI-PC) (133), Toolkit of Instruments to Measure End of life care (TIME) (132). Table 3 shows the properties of identified palliative care or end of life measures that were identified from the publications (104, 121-123).

Two measures were excluded as they were patient-reported. These were the QOLC-E (130) and the mQOLC-E (131). The majority of measures (n=10) were developed and have been assessed as measuring the quality of care received (123), rather than comprehensive symptoms and concerns. They were therefore identified as not suitable for amending. These included EOLD-SWC (125), the FATE (126), the FATE-S (134), the FPCS (127), the FPPFC (135), the QODD (128), the QOD-LTC (129), the QOD-LTC-C (129), and the nursing home version of the TIME (132). The EOLD-CAD (125) was developed to assess comfort at dying in people with advanced dementia. As it specifically measures the comfort during dying and is completed post-death, and not as a clinical assessment tool, it was excluded for adaptation in this study. The RAI-PC (133) was excluded on the basis that no psychometric evaluation had been conducted in people with dementia.

Table 3 Properties of palliative and end of life care measures used for people with dementia or in care homes

Measure name, date of publication, country of origin	Purpose of measure: what does it aim to assess?	Developed for data collection pre or post-death	Psychometric evaluation conducted in people with dementia living in care homes	Developed for people with dementia	Developed for care home setting	Stages of dementia	Requirement for a clinical qualification
EOLD-CAD (125) 2001 US	Family members' perceptions of symptom intensity and conditions common in dying	Post-death: developed as a post-death family-reported outcome measure	Yes	Yes	Yes - Nursing homes, hospitals and homes	End stage dementia – during dying	No – developed for completion by family members
EOLD-SM (125) 2001 US	Family members' perceptions of frequencies of physical and emotional symptoms	Post-death: developed as a post-death family-reported outcome measure. Has also used pre-death	Yes	Yes	Yes - Nursing homes, hospitals and homes	End stage dementia (last 90 days of life, also used in last month and last week)	No – developed for completion by family members
EOLD-SWC (125) 2001 US	Family members' satisfaction with the quality of care provided	Post-death: developed as a post-death family-reported outcome measure. Has also used pre-death	Yes	Yes	Yes - Nursing homes, hospitals and homes	End stage dementia (last 90 days of life, also used in last month and last week)	No – developed for completion by family members
FATE (126) 2008 US	Family members' perceptions of quality of care	Post-death: developed as a post-death family-reported outcome measure	No	No	No – health care settings	Not applicable	No – developed for completion by family members
FATE-S (134) 2010 US	Family members' perceptions quality of care	Post-death: developed as a post-death family-reported outcome measure	Yes	No	No – health care settings	Not applicable	No – developed for completion by family members
FPCS (127) 2004 Canada	Family members' perceptions of quality of care	Post-death: developed as a post-death family-reported outcome measure	Yes	No	Yes	Not applicable	No – developed for completion by family members
FPPFC (135) 2007 US	Family members' perceptions of physician communication during dying	Post-death: developed as a post-death family-reported outcome measure	Yes	No	Yes	Not applicable	No – developed for completion by family members
MSSE (136) 2004 Israel	Health care professionals' perspective of dying in end-stage dementia	Pre-death: developed to be used as part of routine care by health care professional pre-death	Yes	Yes	No – research and treatment centre	End stage dementia	Yes - physician completed

Measure name, date of publication, country of origin	Purpose of measure: what does it aim to assess?	Developed for data collection pre or post-death	Psychometric evaluation conducted in people with dementia living in care homes	Developed for people with dementia	Developed for care home setting	Stages of dementia	Requirement for a clinical qualification
POS (87) 1999 UK	Palliative care symptoms and concerns	Pre-death: developed to be used as part of routine care completed by patients, carers or staff	Yes	No	No – palliative care settings including inpatient, outpatient, day care, home care and primary care	Not applicable	No – developed for completion by staff/health care professionals or patients
QODD (128) 2002 US	Family members' perceptions of quality of dying	Post-death: developed as a post-death family-reported outcome measure	No	No	Yes - multiple settings including nursing homes	Not applicable	No – developed for completion by family members
QOD-LTC (129) 2007 US	Family members' and staff perceptions of psychosocial quality of dying	Post-death: developed as a post-death family- and staff-reported outcome measure	Yes	Yes	Yes	All	No – developed for completion by family members
QOD-LTC-C (129) 2007 US	Family members' and staff perceptions of psychosocial quality of dying	Post-death: developed as a post-death family- and staff-reported outcome measure	No	No	Yes	Not applicable	No – developed for completion by family members
QOLC-E (130) 2005 China	Patients' perceptions of quality at end of life	Pre-death: developed as a patient-reported outcome measure	No	No	Yes	Not applicable	No – developed for completion by patients
mQOLC-E (131) 2008 China	Patients' perceptions of quality at end of life	Pre-death: developed as a patient-reported outcome measure	No	No	Yes - multiple settings including care homes	Not applicable	No – developed for completion by patients
RAI-PC (133) 2003 US, Czech Republic and Sweden	Palliative care needs	Pre-death: developed to be used as part of routine care completed by staff	No	No	Yes - multiple settings including care homes	Not applicable	Yes – health care professional, usually nurse completed
TIME (132) 2001 US	Family members' perceptions of dying process	Post-death: developed as a post-death family-reported outcome measure	Yes	No	Yes	Not applicable	No – developed for completion by family members

EOLD: End of Life in Dementia; EOLD-SM: Symptom Management; EOLD-SWC: Satisfaction With Care; EOLD-CAD: Comfort Assessment in Dying; FATE: Family Assessment of Treatment at the End of life; FATE-S: Family Assessment of Treatment at the End of life - Short version; FPCS: Family Perceptions of Care Scale; FPPFC: Family Perceptions of Physician-Family caregiver Communication; MSSE: Mini Suffering State Examination; POS: Palliative care Outcome Scale; QODD: Quality of Dying and Death; QOD-LTC: Quality of Dying in Long Term Care; QOD-LTC-C: Quality of Dying in Long Term Care – Cognitively intact; QOLC-E: Quality Of Life Concerns in End of life questionnaire; mQOLC-E: modified Quality Of Life Concerns in End of life questionnaire; RAI-PC: Resident Assessment Instrument for Palliative Care; TIME: Toolkit of Instruments to Measure End of life care; UK: United Kingdom; US: United States

Three measures remained as potentially suitable for adaptation: EOLD-SM (125), the MSSE (136) and the POS (87). They warranted further examination as to their suitability for adaptation to assess comprehensive symptoms and concerns in people with dementia living in care homes by care home staff. Reference searches identified 12 additional papers for inclusion in the review (Table 4). One potentially eligible study was not included as it was published in Dutch (138), and two were excluded as they were conference abstracts (137, 139).

Table 4 Study details of identified studies from reference list searches

Lead author, date and country	Measure(s) used	Study design	Setting	Population	Administered	Administered pre- or post-death
Aminoff, 2004 Israel (136)	MSSE	Psychometric evaluation	Research and treatment Medical centre	People with severe end-stage dementia n=103	Physicians	Pre-death
Aminoff, 2005 Israel (140)	MSSE	Prospective observational study	General geriatric department of a tertiary hospital	People with severe end-stage dementia n=71	Not stated	Pre-death
Aminoff, 2006 Israel (141)	MSSE	Prospective cohort study	Division of geriatric medicine in a general hospital	People with severe end-stage dementia n=252	Not stated	Pre-death
Bausewein, 2005 Germany and Austria (142)	POS	Psychometric evaluation	Palliative care settings including hospital support team, palliative care unit, hospice, pain clinic, GP practice/home care in Germany and Austria	Patients receiving palliative care n=118	Self-completed by patients and staff/health care professional completed	Pre-death
Brandt, 2005 the Netherlands (143)	POS	Prospective observational study	Nursing homes	Terminally ill nursing home patients with and without dementia (all stages) n=448	Nursing home physicians and nurses	Pre-death
Cohen, 2012 US and the Netherlands (144)	EOLD-SM MSSE POS	Post-death family interviews and self-administered questionnaires	Care homes	People who died with dementia (all stages) in long-term care n=196	Administered to family members or self-administered by family members	Post-death
Eisenchlas, 2008 Argentina (145)	POS	Cross-cultural adaptation and psychometric evaluation	Palliative care settings including inpatient wards, home care, day care, and primary care	Patients receiving palliative care n=65	Self-completed by patients and staff/health care professional completed	Pre-death
Hearn, 1999 UK (87)	POS	Measure development and psychometric evaluation	Palliative care settings including inpatient, outpatient, day care, home care and primary care	Palliative care patients n=148	Self-completed by patients and staff/health care professional completed	Pre-death
Kiely, 2006, US (146)	EOLD-SM	Psychometric evaluation	Nursing homes	Nursing home residents with advanced dementia and proxies n=189	Trained research assistants interviewed nurses	Pre-death

Lead author, date and country	Measure(s) used	Study design	Setting	Population	Administered	Administered pre- or post-death
van der Steen, 2009 US and the Netherlands (147)	EOLD-SM	Mortality follow back study	Nursing homes	Nursing home residents who died with dementia (all stages) N=130	Self-completed by family members	Post-death
van der Steen, 2009, the Netherlands (148)	EOLD-SM	Post-death family self-administered questionnaires	Nursing homes	People who died with dementia in nursing homes N=48	Self-completed by family members	Post-death
Volicer, 2001, US (125) and Volicer, 2003, US (149)	EOLD-SM	Measure development and psychometric evaluation, developed from postal survey	Geriatric Research Educations Clinical Centres and National Institute on Ageing Alzheimer's Disease Centres	People who died with dementia	Self-completed by family members N=156	Post-death

EOLD-SM: Symptom Management; MSSE: Mini Suffering State Examination; POS: Palliative care Outcome Scale; UK: United Kingdom; US: United States

The EOLD-SM (125) is a nine-item scale, with a six-point Likert scale response option from 0 to 5 comprising: daily, several days a week, once a week, 2 or 3 days a month, once a month, or never. EOLD-SM was developed for completion by family members and therefore does not require a clinical qualification. It measures symptom burden experienced at the end of life for people dying with advanced dementia, and exploratory factor analysis in people in care homes who died with dementia (n=105) revealed two subscales: psychological symptoms (including *'Calm', 'Depression', 'Fear', 'Anxiety', 'Agitation',* and *'Resistiveness to care'*)', and physical symptoms (including *'Pain', 'Shortness of breath',* and *'Skin breakdown'*) (125). Cronbach's alpha of the total measure and psychological symptoms scored positively (106) at 0.78 and 0.81 respectively. However, Cronbach's alpha of physical symptoms was poor at 0.47 (106). To test validity, EOLD-SM total scores and subscale scores were compared to EOLD-SWC and EOLD-CAD total and subscale scores. Correlation coefficients ranged from 0.20 to 0.66 (106). However, without a priori hypotheses on the expected strengths of associations, it is difficult to interpret these results (106). EOLD-SM has also been psychometrically evaluated pre-death in people with advanced dementia living in care homes (n=189) (146). In this study, trained research assistants administered EOLD-SM to nurses with primary care responsibility at baseline and quarterly for 18 months, and post death if the person with dementia died during the study period. Cronbach's

alpha for the total scale was 0.68 (n=176). Validity testing was conducting by examining the strength of association between EOLD-SM and the Quality of Life in Late-Stage Dementia measure (QUALID) (150) administered to nurses at baseline (n=174). Pearson and Spearman correlation coefficients were -0.64 and -0.63 respectively. No a priori hypotheses were stated, and EOLD-SM was not tested against any other measures. As a consequence, it is not possible to determine the strength of validity from this study (106). Another study examined EOLD-SM scores of nurses and family members of people who died with dementia in nursing homes (n=48). Concordance correlation coefficients (CCC) between nurses and family members was 0.42, with family members reporting slightly higher symptom management than nurses (148). The EOLD-SM has also been used to compare family members' post-death evaluations of end of life of people with dementia in nursing homes in the Netherlands (n=54) and US (n=76). Although not a validation study, the authors found small but consistent and systematic differences between countries and conclude that this may suggest validity and sensitivity of EOLD-SM to detect differences between countries or timeframes (147). EOLD-SM has been translated into Dutch and validated in both United States (US) (104, 125, 146) and the Netherlands (122, 148). Its limitations are that it aims to assess physical and psychological symptoms but not the full range of physical symptoms and emotional, social, existential, and family concerns that people with dementia may experience; it was developed for people dying with advanced dementia rather than throughout the disease trajectory; and primarily as an outcome measure for research purposes, to be completed post-death, rather than for use in routine care by care home staff.

The MSSE (136) was also developed for people with advanced dementia. The MSSE aims to assess suffering and as such does not assess the full extent of comprehensive symptoms and concerns to inform management of these. It comprises 10 dichotomous items including *'Not calm', 'Screams', 'Pain', 'Decubitus ulcers', 'Malnutrition', 'Eating disorders', 'Invasive action', 'Unstable medical condition', 'Suffering according to medical opinion', 'Suffering according to family opinion'.* The MSSE was originally developed to be used by physicians to inform clinical care in hospital settings. As such, its use by care home staff without a clinical qualification is less established. In addition, one of the items *'Malnutrition'* requires objective laboratory data to inform the response, thus limiting its suitability for completion by care home staff. It has, however, undergone psychometric evaluation with family members (122) in the Netherlands, and in another

study, its terminology was adapted for use by family members (144). It was originally developed and psychometrically evaluated in a hospital setting in Israel (136). In this study, 103 patients with end-stage dementia were recruited, and two physicians independently examined patients and completed the MSSE. Cronbach's alpha for each of the physicians was 0.74 and 0.72 indicating strong internal consistency (136). Total score kappa between both physicians was 0.79, with individual item kappa of 0.62 to 0.97. MSSE correlation with EOLD-CAD total scores was -0.80 and with EOLD-CAD subscales of wellbeing: r=0.72, emotional distress: r=-0.65, physical distress: r=-0.76, dying symptoms: r=-0.50. The MSSE has been translated and psychometrically evaluated in care homes in the Netherlands (122) and in the US (104, 136), and has been used in two prospective studies to evaluate suffering and palliative care need in people with end stage dementia in general hospitals (140, 141).

The POS was originally developed for people with cancer, and was developed for both research and clinical purposes with established clinical utility (87). It has been used in people with dementia in care homes and found to be appropriate and feasible for the majority of participants except for those with severe dementia, with the authors concluding that POS is suitable for people with dementia in care homes (143). POS comprises 10 items including *'pain', 'other symptoms e.g. nausea, coughing or constipation', 'anxiety or worry about illness or treatment', 'family anxiety or worry', 'information for patient or family', 'ability to share feelings', 'life worth living', 'feeling good about themselves', 'time wasted on appointments', 'practical matters resulting from illness'.* The items are rated from 0 to 4 with higher scores reflecting worse problems. Originally, a patient and a staff/health care professional version were developed and these measures were psychometrically evaluated in multiple community and inpatient palliative care settings in predominantly people with cancer, but also people with stroke and motor neurone disease (87). In this development and psychometric evaluation, item weighted kappa agreement between patient- and staff/health care professional-completed measures at first assessment (n=145 matched assessments) ranged from 0.22 to 0.56, second assessment (n=97 matched assessments) ranged from 0.32 to 0.58, and third assessment (n=66 matched assessments) 0.28 to 0.58. Test-retest reliability was limited by a small sample size (n=34) (106) with item kappa ranging from -0.08 to 0.62. Internal consistency for the patient-completed measure (n=128) was 0.65 and for the staff/health care professional-completed measure (n=308) was 0.70. Construct

validity was examined through correlation between staff/health care professional-completed POS and the Support Team Assessment Schedule (STAS) (n=43) and patient-completed POS and the European Organisation for Research on Cancer Treatment Quality of Life Questionnaire (EORTC QLQ-C30) (n=29). POS items were grouped into subscales with expected correlations between subscales and total scores on the STAS and EORTC QLQ-C30. Spearman's rho correlation coefficients ranged from 0.43 to 0.53 between patient-completed POS and EORTC QLQ-C30 (n=29) and from 0.51 to 0.80 between staff/health care professional-completed POS and STAS (n=43). However, the validity testing is limited by the small sample sizes (106). The mean time taken to complete POS for staff/health care professionals was 5.7 minutes which decreased to under 4 minutes by the third assessment, with none taking longer than 10 minutes. In the identified studies from this review, POS has been translated and cross-cultural validated into German in Germany and Austria (142), and Spanish in Argentina (145), although not in populations of people with dementia. The limitations of POS is that it was not developed for people with dementia in care homes, and therefore includes items that may be of less relevance to people with dementia living in care homes (143). This indicates a requirement for a disease-specific version for people with dementia generally, and specifically for those living in care homes. It has, however, undergone psychometric evaluation for people with dementia living in care homes in the Netherlands and US (104, 122).

In a validation study conducted in the Netherlands all three measures were translated into Dutch. The MSSE (136) was found to be the most valid and reliable at assessing quality of death in nursing home residents with dementia, with correlation coefficients with other quality of death measures (EOLD-CAD, EOLD-SM, POS, QOD-LTC) ranging from r=0.36-0.58[1] for family-completed measures (n=70) and r=0.32-0.70[1] for professional-completed measures (n=103). MSSE correlation with 'gold-standard' physician-completed before death discomfort and pain measures, the Discomfort Scale – Dementia Alzheimer's Type (DS-DAT) (151) and the Pain Assessment in Advanced Dementia (PAINAD) (152) were r=0.09 and r=0.14[1] (n=24) respectively. In comparison the POS was assessed as the weakest measure to assess quality of death with correlation coefficients with other measures (EOLD-CAD, EOLD-SM, MSSE, QOD-LTC) ranging from r=0.38-0.59[1] for family completed measures (n=70) and r=0.41-0.56[1] for professional

[1] Directions not shown but both positive and negative values due to different scoring directions

completed measures (n=103). POS correlation with DS-DAT (151) was r=0.08 and PAINAD (152) was r=0.03 (n=24). Without clear a priori hypotheses stating expected strengths of correlations, it is difficult to interpret these results (106). They are, however, perhaps not unsurprising as POS measures a much more comprehensive construct than either discomfort or pain, has not been developed with dementia specific items for this population, and was not developed to be completed retrospectively post-death.

In terms of reliability, there was no significant difference between family and professional completed measures for MSSE (p=0.88) with CCC (95% confidence interval (CI)) of 0.50 (0.25-0.68), Cohen's d effect size=0.02 (n=54). Similarly, there was no significant difference between physician and nurse completed measures for MSSE (p=0.08), CCC (95% CI) of 0.40 (0.08-0.64) (n=33). There was no significant difference between family and professional-completed measures for POS (p=0.82) with CCC (95% CI) of 0.23 (-0.09-0.50), Cohen's d effect size=0.18 (n=54). There was, however, a significant difference between physician and nurse completed measures for POS (p=0.03), CCC (95% CI) of 0.25 (-0.07-0.54) (n=33). Overall, CCC reliability estimates for EOLD-SM, MSSE and POS were fair to moderate (0.21-0.50) (122). In this same study (104, 122), average percent missing data for EOLD-SM was 17.8% and 2.9% missing for family and health care professionals respectively; for MSSE 6.9% and 3.2% respectively; and for POS 16.3% and 4.8% respectively.

A study utilising data from the Netherlands validation study reported above (122) and a validation study conducted in US sought to identify the best instruments to measure quality of end of life care and quality of dying in care homes (104). In this study, the measures were rated as positive, intermediate or negative against criteria to determine feasibility, validity and reliability. In both studies, measures were administered post-death. Unlike the Netherlands study, in the US study measures were only administered to family members and not completed by health care professionals, and residents who had died were both cognitively intact and cognitively impaired. In terms of feasibility, the MSSE scored positively in the Netherlands and US for 'relevance and ease of use', 'level of completion' and 'suitability for target population'. The EOLD-SM and POS had similar levels of intermediate and positive ratings, with EOLD-SM scoring higher for 'level of completion' than POS, and POS scoring higher on 'relevance and ease of use' than EOLD-SM.

In terms of convergent validity in relation to overall rating of quality of dying, all three measures scored intermediate (r=0.30-0.50) in the Netherlands while in the US, POS scored intermediate and EOLD-SM and MSSE scored negatively (r≤-.30). In terms of convergent validity in relation to other measures of a similar construct, in the US all measures scored positive (total score correlates r≥0.50 with total score of two or measures of the same construct), while in the US, the MSSE and POS scored positive and the EOLD-SM scored intermediate (total score correlates r≥0.50 with only one other measure of the same construct).

There are limitations to this review. The first is that it is not a systematic review and some measures may have been missed. However, as recent reviews had been published, conducting a full systematic review was not justified. In addition, the aim of this review was to identify and critically appraise the most established measures, rather than identify all measures used with this population. Conducting reference searches of the reviews allowed identification of further data on the psychometric properties and feasibility and acceptability in routine care. However, using this method may have resulted in some studies being missed. Another limitation is that only English-language papers were included in this review meaning that any additional data on the measures used in other countries and languages were not included (138).

3.3.3.1 Final selection of measure:

Table 5 Summary of measures meeting the stage 2 criteria for selection

Eligibility criteria	**EOLD-SM**	**MSSE**	**POS**
i. Comprehensive assessment of symptoms and concerns	x	x	✓
i. Relevant throughout the dementia disease trajectory	x	x	x
ii. Established as a clinical assessment measure	x	✓	✓
iii. No requirement for a clinical qualification	✓	x/✓	✓
iv. Psychometric evaluation in setting and population	x/✓	x/✓	x/✓
v. Established internationally and cross-culturally	✓	✓	✓
v. Freely accessible and available	N/K	N/K	✓

✓ - meets criterion, x – does not meet criterion, x/✓ - mixed evidence or partially meets criterion, N/K from review or measure description

Table 5 shows how each measure is rated against the five stage 2 criteria detailed in section 3.3.2.2. For clarity, criteria two and five are separated. Based on the review and evaluations, POS was selected as the measure for adaptation as it was the measure that meets the most criteria. All three measures have relative strengths and weaknesses. Importantly, POS is the only measure that has been developed to assess comprehensive physical symptoms, and emotional, social, existential and family concerns. (87). Another important strength was that it was originally

developed for use in, and is now well-established in practice to inform and aid care, and that it was not just developed for research purposes (87, 153). Unlike the EOLD-SM and MSSE, the POS has not been developed specifically for people with dementia. This is both a strength as a measure for generic palliative care populations with additional disease-specific items allows for comparisons between populations (84); and may also be more suited to older people with dementia and multi-morbidities. However, it is a disadvantage in that it does not incorporate dementia-specific symptoms and concerns experienced by this population. Conversely, the EOLD-SM and the MSSE have just been developed for the end-of-life for people with advanced dementia, and not for the full dementia trajectory. None of them are therefore developed to be used for people with dementia and multi-morbidities throughout the disease trajectory and all would require some adaptation and psychometric evaluation in this population. MSSE has strongest and most established psychometric properties in this population but assesses suffering during end stage dementia rather than comprehensive symptoms and concerns experienced by people with dementia and multi-morbidities throughout the disease trajectory. This means that it is the least suited to adaptation, as it does not aim to assess comprehensive symptoms and concerns but instead signs of distress for example, *screaming*. It would therefore require substantial changes resulting in an overall change of the measure aim and of its construct. Additionally, although MSSE was also developed for clinical purposes, it was developed for and has also predominantly been evaluated in hospital settings completed by physicians (136, 140, 141). EOLD-SM does assess physical and psychological symptoms and concerns, but a major limitation is that it was developed for research purposes as a post-death outcome measure for the dying phase. POS was therefore the best suited for adaptation, meeting the most criteria.

3.4 POS and the Integrated Palliative care Outcome Scale (IPOS)

POS is one of the measures in the POS family of measures, and there are ongoing developments (154). A patient, staff/health care professional and carer version have been developed (154) and POS has been translated into a number of languages including German (142) and Spanish (145), and cross-culturally validated including, for example, the African Palliative Care Association African POS (155). As such, the psychometric properties of POS have been extensively tested in diverse populations and settings (156). POS, its disease-specific and translated versions, and resources are all freely available online (154), thus maximising its **availability** internationally.

POS has been used in an action research project in a nursing home and hospice to examine the facilitators and barriers to implementation (157). The results of this study revealed that POS had been easily incorporated into routine care in nursing homes, and was quick and easy to use (157). In addition, nursing home staff, including those without a clinical qualification, overwhelmingly reported that using POS routinely benefitted resident care (157).

The POS family of measures is ongoing development, with new versions and translations regularly being developed (153). These are conducted or overseen by the POS development group, based at the Cicely Saunders Institute. A strength of adapting the POS was the ability to draw upon the scientific expertise of the POS development team in developing and refining the measure for dementia, and access to the most recent POS developments. One recent development of POS is the IPOS (158). The IPOS was developed following requests from health care professionals to combine the POS and POS-symptom module (POS-S). The result is a 10 question measure that examines a person's main concerns, common symptoms, and emotional, social and existential, and family concerns (158). As the aim of this study was to develop a comprehensive measure to assess symptoms, the most recent POS development, the IPOS was chosen for adaptation. See Appendix B for copies of POS, POS-S and IPOS.

3.5 Summary of key points, gaps and next steps

This chapter reviews palliative care measures and their potential to be developed as a comprehensive measure to improve assessment and management of symptoms and concerns for people with dementia. In particular, the methods used in the chapter identify **comprehensive proxy-reported measures of physical symptoms and emotional, social, existential and family concerns** that have been psychometrically evaluated in people with dementia, before death.

Three measures, EOLD-SM, MSSE, and POS, were identified and reviewed in detail with regards to their **validity, reliability, responsiveness,** and **interpretability.** In addition, their **acceptability and feasibility** for use by care home staff without a clinical qualification for people throughout the disease trajectory living in care homes were also examined, as well as how well-established they are cross-culturally and how easily **available** they are.

All three measures were identified as requiring some adaptation to ensure comprehensiveness and relevance for people with all stages of dementia living in care homes. The POS, as the only measure developed to assess comprehensive physical symptoms, and emotional, social and existential, and family concerns as part of routine care, was identified as the most suited measure for adaptation. The IPOS is a new development integrating POS and POS–S to assess comprehensive symptoms and concerns experienced by palliative care patients, and identified as the most suitable version of the POS family of members for adaptation. However, neither POS nor IPOS were developed for people with dementia.

To adapt IPOS for people with dementia living in care homes requires examination of the content validity to determine items of less relevance requiring adaptation or removal, and possible addition of important items to ensure that it is comprehensive for people with dementia and multi-morbidities (10).

Furthermore, this newly developed measure is being developed as a complex intervention to improve comprehensive assessment and management of symptoms and concerns of people with dementia in residential care homes and their family members. It is therefore important to gain an understanding of the likely mechanisms of action within the residential care home context; the potential benefit to people with dementia and their families; its feasibility and acceptability for use in routine care; and implementation requirements from early in the intervention development phase (2, 5, 93).

4. Methods: general

4.1 Introduction

This chapter presents the study aim and objectives, as well as the study design, the rationale for the choice of methods chosen, and ethical issues.

4.2 Aim

To develop and conduct a preliminary evaluation of the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem) to improve assessment and management of symptoms and concerns for people with dementia in residential care homes.

4.3 Objectives

IPOS-Dem pre-clinical objectives:

1. To identify common symptoms and concerns experienced by people with dementia, and items of low relevance in POS/IPOS to construct the measure, IPOS-Dem Version 1.

IPOS-Dem development/pre-implementation objectives:

2. To explore the content validity of IPOS-Dem Version 1 to identify additional relevant symptoms and concerns, and redundant items, and refine the measure resulting in IPOS-Dem Version 2.
3. To determine the acceptability and ease of comprehension of IPOS-Dem Version 2 and its manual to care home staff and make necessary refinements based on the results, resulting in IPOS-Dem Version 3 ready for evaluation phase.
4. To gain an understanding of the residential care home context, the likely mechanisms of action, implementation requirements, and acceptability and feasibility of IPOS-Dem in the development phase to inform its use in routine care in preparation for evaluation phase.

IPOS-Dem evaluation/post-implementation objectives:

5. To understand the mechanisms of action and potential benefit of IPOS-Dem used in routine care of people with dementia within the residential care home context.

6. To gain an understanding of the implementation requirements of IPOS-Dem into routine care of people with dementia.
7. To test the acceptability and feasibility of IPOS-Dem in routine care of people with dementia.

4.4 Study design and overview of methods

The overall study design used a mixed methods approach with pre- and post-implementation phases, informed by MRC guidance (2, 3, 93) and Methods of Researching End of Life Care (MORECare) statement (159). The study is a development and preliminary evaluation (process and feasibility evaluation) of a complex intervention to refine and understand the intervention within the residential care home context in preparation for testing the methods of, and conducting a full trial of effectiveness (2, 3, 93). Stages of the overall study design, linked to the study objectives, research methods, and outputs are presented in Figure 5.

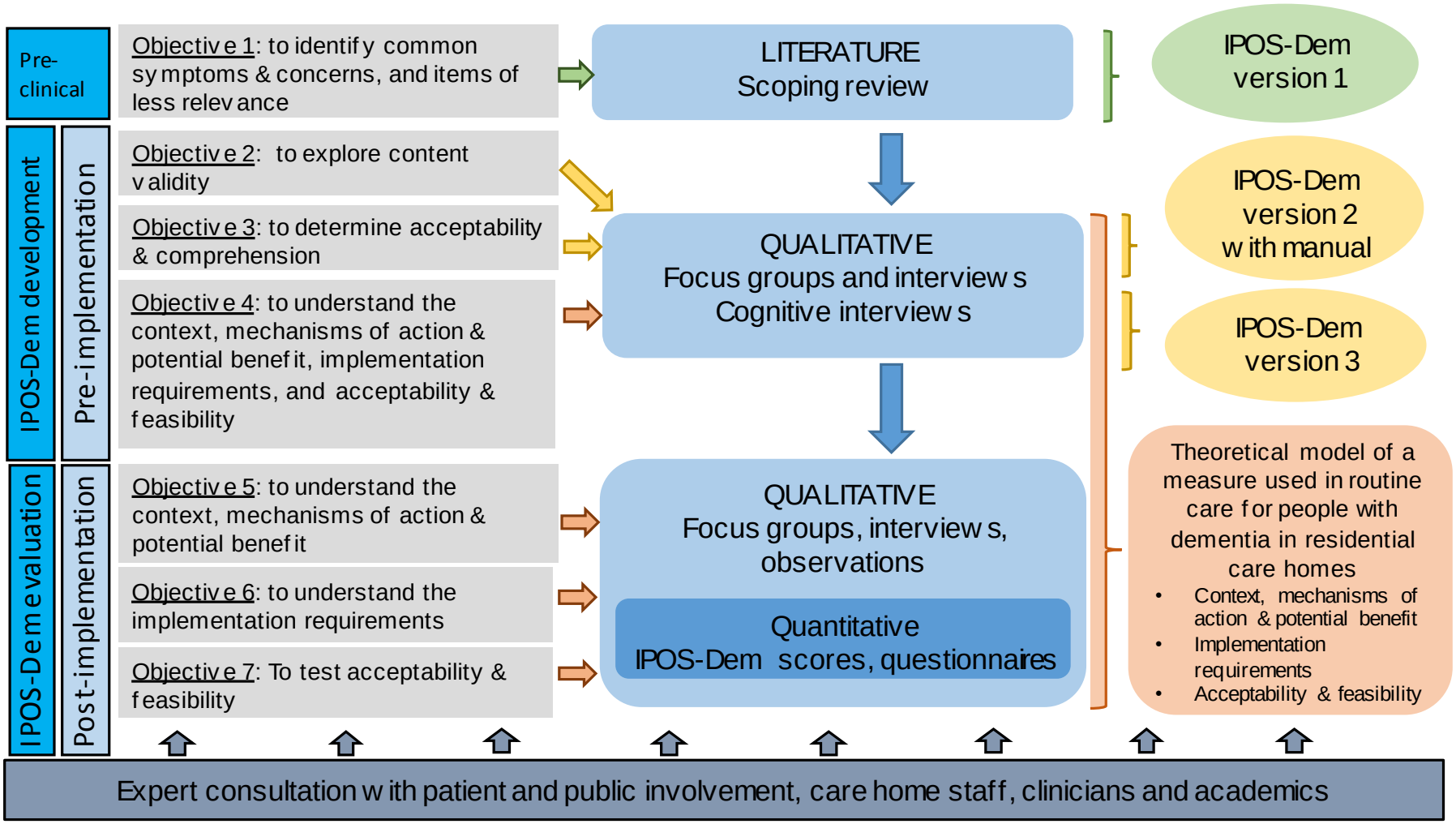


Figure 5 Overview of study design, objectives, methods and study outputs

4.5 Medical Research Council guidance and Methods Of Researching End of life Care statement

4.5.1 Medical Research Council guidance for developing and evaluating complex interventions

The MRC guidance published in 2000 was developed with the recognition that health care services regularly use complex interventions. The guidance proposed a framework of sequential phases to guide the process of developing and evaluating a complex intervention, with each phase building upon the next (93). However, limitations of this framework were subsequently identified and an updated guidance was published in 2008 (2). The updated guidance addressed requirements for: (i) more focus on initial piloting and development work (160), (ii) a more iterative and less sequential model (161), (iii) integration of process and outcome evaluation (162), (iv) recognition that interventions may work best when adapted to contexts (163), (v) and greater use of insights from theory of complex adaptive systems (164). Within the new guidance, an updated model (Figure 6) was presented. The four phases in the new model are: development, feasibility/piloting, evaluation, and implementation. These may not necessarily be linear.

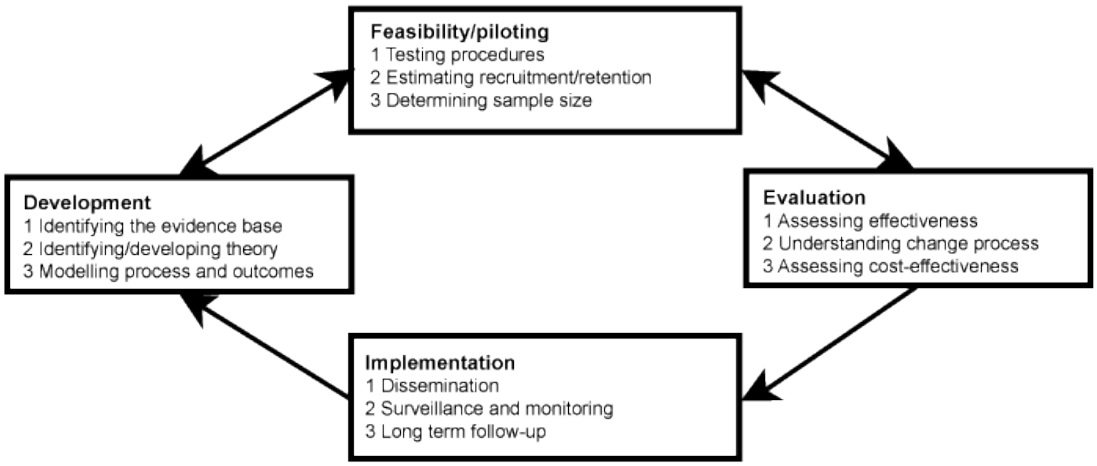


Figure 6 MRC guidance 2008 Key elements of the development and evaluation process (2)

The 2008 MRC guidance recommends that adequate development of the intervention is essential before a large-scale evaluation is conducted. Development of an intervention involves three components. The first, *Identifying the evidence base,* includes conducting a systematic review to determine what is known about similar interventions. The second involves *Identifying and developing theory.* Essential to this is gaining a theoretical understanding of how the intervention is likely to change processes, and is gained from existing evidence and theory. If necessary,

additional primary research may be carried out to inform theory development. Finally in *Modelling process and outcomes* a number of studies may be required to refine the intervention.

The feasibility/piloting phase allows for the opportunity to examine components of the intervention (such as *acceptability, feasibility*), and aspects of the testing procedures (such as recruitment and retention and effect size). Feasibility/piloting may also provide valuable insights and understanding of the *context* of intervention delivery (4). It is essential that intervention development, and feasibility/piloting is adequately conducted before proceeding to full-scale evaluation (2).

In 2015, further MRC guidance was published to address the need for guidance in conducting process evaluations (3). A process evaluation is defined as:

> 'A study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors. Process evaluation is complementary to, but not a substitute for, high quality outcomes evaluation' (5)

The process evaluation framework built upon the 2008 MRC guidance (2), but emphasised the relationship between *implementation*, *mechanisms of action* and *context* (Figure 7). Delivery of a complex intervention is usually tailored to different contexts. By examining *what* is delivered in practice against the intervention theory, greater understanding can be gained as to which aspects of the intervention can be modified to fit the context, and which pose a threat to fidelity (165, 166). Process evaluations provide the opportunity to examine *how* interventions are delivered, thus providing important data on how the intervention can be replicated in other settings.

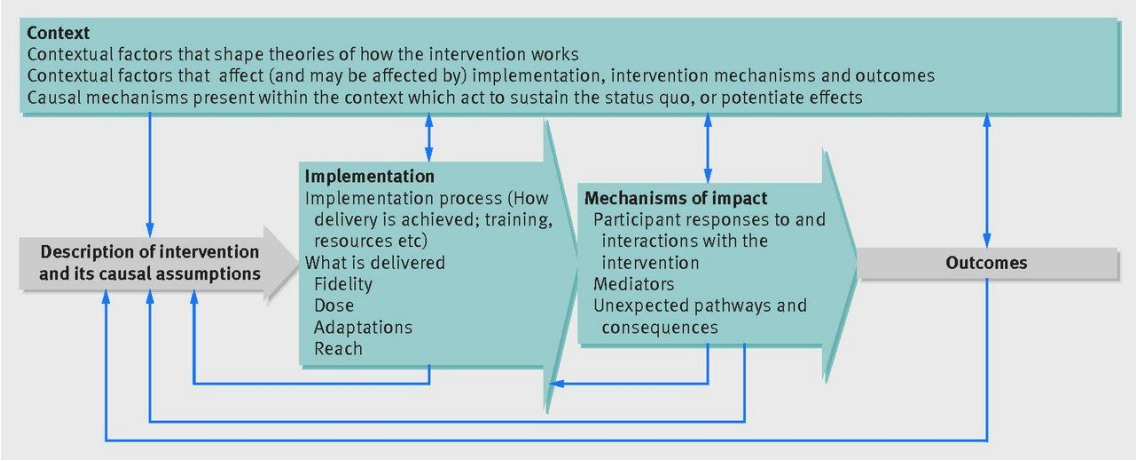


Figure 7 MRC guidance 2015: Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation. Investigation of these components is shaped by a clear intervention description and informs interpretation of outcomes) (3)

Furthermore, process evaluations provide the opportunity to examine the hypothesised mechanisms of action (3) to gain a greater understanding into complex pathways, and identify any unexpected mechanisms of action (167). Finally, they can provide insight into the impact of context, defined as anything external to the intervention that may either impede or assist implementation or its consequences. Delivery of intervention may vary between contexts. However, even if delivery is the same, the context may impact on the effect of the intervention (164). Understanding of context and how it interacts with the intervention is essential, both to interpret findings and to understand generalisability of the intervention (3). In particular, it is essential to understand which aspects of the intervention should be standardised as the mechanisms of action and which components and/or delivery of components need to be adapted for local contexts (165).

This study was informed by the 2000 and 2008 MRC guidance. The 2015 guidance was published after this study was planned and designed. However, objectives of the study were to understand the likely mechanisms of action and how these may occur within the context, feasibility and acceptability, and the implementation requirements of the intervention. The 2015 process evaluation guidance therefore provided a useful framework and language for articulating the methods, and to contextualise it within the process of developing and evaluating complex interventions. In particular, the 2015 guidance informed how process evaluations are combined in feasibility and pilot testing to provide the opportunity to examine the feasibility, acceptability and implementation requirements (5).

The aim of this study was, as informed by the MRC guidance, the development and preliminary evaluation of a complex intervention, IPOS-Dem, to support assessment and management of symptoms and concerns. Preliminary evaluation comprised a feasibility and process evaluation of the intervention, prior to testing of methods and full evaluation of effectiveness. The feasibility and process evaluation incorporated an examination of the residential care home context, the likely mechanisms of action, acceptability and feasibility, and implementation requirements of the intervention. In keeping with the 2008 guidance, this study followed a less linear approach, with feasibility and process evaluation occurring both during the development/pre-implementation and evaluation/post-implementation phases (Figure 5). This crucially allowed examination of the

context, mechanisms of action and implementation requirements during the development of the intervention.

The study started with a pre-clinical (93) literature review which informed the development IPOS-Dem Version 1 (Objective 1). The pre-clinical phase in the MRC guidance 2000 refers to the first, or theoretical, stage of intervention development (93). A development/pre-implementation qualitative phase was then conducted to further develop and refine IPOS-Dem, (Objectives 2 and 3); and explore the likely mechanisms of action within the residential care home context, and gain an early understanding of its acceptability and feasibility, and likely implementation requirements during the development of the intervention (Objective 4). An evaluation/post-implementation mixed-methods phase followed where IPOS-Dem was implemented into routine care of participants with dementia to gain a deeper understanding of the likely mechanisms of action and how the intervention may work in the residential care home context (Objective 5) as well as an understanding of the implementation requirements (Objective 6), and the acceptability and feasibility of the intervention (Objective 7). The theoretical model demonstrating likely mechanisms of action, requirements for acceptability and feasibility of the intervention, and implementation requirements was then refined as a greater understanding was obtained from development/pre-implementation and evaluation/post-implementation feasibility and process evaluation. The focus of this study is on the development of an intervention and an understanding of its mechanisms of action, acceptability, feasibility and implementation requirements for use in routine care of people with dementia living in care homes. In doing so, the study seeks to establish how the intervention works within context and how it should be adapted to context. Furthermore, the study undertakes to understand the complexity of multi-agency working within residential care homes and external to residential care homes. This includes the importance of relationships between care home staff, and between care home staff, family members, and health care staff; taking into consideration known barriers that have previously been identified (60, 62-65).

4.5.2 MORECare statement

The MORECare collaboration was established by the MRC and National Institute of Health Research (NIHR) in response to the challenges of conducting high quality end of life care (EoLC) studies. The MORECare statement defines EoLC as:

> 'the total or holistic care of a person during the last part of their life, from the point at which a person's health is in a progressive state of decline, usually in the last months, weeks or days of life.' (159, 168)

MORECare builds upon the MRC guidance to provide guidance on best practice for undertaking EoLC research (159). In developing the statement, the MORECare collaboration conducted systematic reviews, transparent expert consultations and stakeholder workshops to identify challenges in undertaking high quality EoLC research; and to identify best practice. MORECare identified five areas in EoLC research that needed addressing: (i) ethics (169), (ii) statistics (managing missing data, attrition and response shift) (170), (iii) outcome measurement (124), (iv) mixed methods research (171), and (v) health economics (172). In addition, MORECare identified three shortcomings of the MRC guidance (159):

(i) Moving from feasibility and piloting to implementation without robust evaluation. In particular, the requirement that implementation be evaluated at all phases, rather than at the end. This ensures that the intervention is feasible with an understanding of context, and that implementation processes are known and understood.

(ii) Failing to evaluate both feasibility of intervention and feasibility of research methods at the same time.

(iii) A lack of theoretical framework underpinning the intervention.

The MORECare statement addresses these problems, recommending a series of steps in the development and evaluation of EoLC interventions (Figure 8).

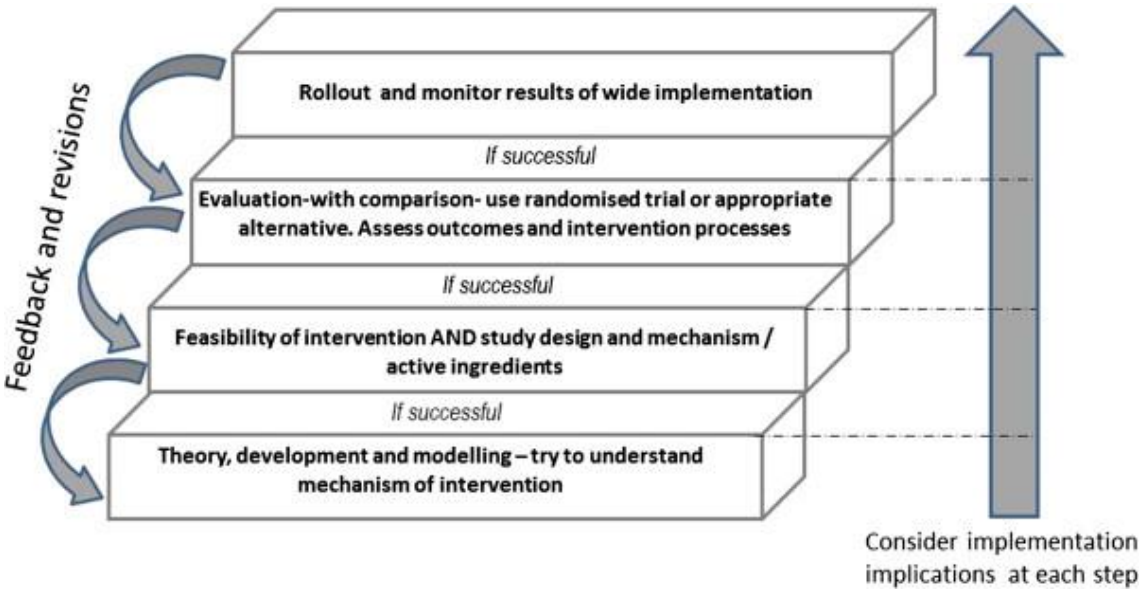


Figure 8 MORECare statement key steps in developing and evaluating EoLC interventions

The MORECare statement also produced a checklist of components requiring consideration when designing and conducting EoLC studies. This study drew upon this checklist with a particular focus on (i) the study team to ensure that the appropriate experts were consulted in the planning and conducting of the study; (ii) ethics – including applying the Mental Capacity Act (MCA) (173) in recruiting and conducting research with people with dementia, (iii) consideration, reporting and management of attrition and missing data, (iv) use of mixed methods research, and (v) consideration of implementation requirements from the outset.

As the focus of the study is on the development and feasibility and process evaluation of IPOS-Dem, the study does not aim to test the feasibility of methods for a full evaluation of effectiveness, despite the MORECare statement's recommendation to do so. However, it was beyond the remit of this study to do so.

The MORECare statement, with its focus on the challenges and requirements for palliative and end of life care research informed methods of this study. The MORECare statement alongside the MRC guidance was used to inform the design and conduct of the study.

4.5.3 How the MRC guidance and MORECare statement informed this study

The study was a **development, feasibility** and **process evaluation** of a complex intervention (93). Based on the MRC guidance and MORECare statement, particular attention was paid to the following in informing the overall aim, objectives and study design:

(i) **Theoretical model underpinning intervention** (159). As detailed in Chapter 1, this study commenced with the development of a theoretical model. The model was developed based on existing models of how measures used in routine health care may improve outcomes (100, 102), detailing the expected mechanisms of action. It was also developed based on existing knowledge of the context of residential care homes, the population of people with dementia who may be unable to express their wishes and concerns, and the many groups of people who may be involved in care (including family members, care home staff, and health care professionals) (50, 63, 65, 103, 174, 175). Intervention components (acceptability and feasibility) and implementation requirements were also considered within the theoretical model. The model underpinned the entirety of the study.

(ii) **Modelling and understanding the mechanisms of action and how they may impact on outcomes** (2, 3, 93, 159). The theoretical model was examined throughout the study. Initially through a developmental qualitative phase, and then through a mixed-methods evaluation phase where IPOS-Dem was implemented into routine care. Expected and unexpected mechanisms of action were identified. The theoretical model was refined to detail the mechanisms of action and their potential impact on outcomes as a result of the study findings. Attention was also paid to how the mechanisms of action worked within the residential care home context.

(iii) **Implementation requirements of the intervention.** The study was not intended to be an implementation one and the focus of the study was on developing and evaluating the intervention. Nonetheless, the implementation requirements of IPOS-Dem were considered from the outset and throughout the study (3, 159). The implementation requirements of IPOS-Dem were incorporated into the initial theoretical model and were examined throughout the study phases, taking into account the residential care home context.

(iv) **The impact of the care home culture on the on delivery of the intervention and outcomes** (3, 159). Froggatt and colleagues (176) suggest that traditional qualitative

and quantitative methodologies could be criticised for not taking the care home culture into consideration and that there is therefore little attention to how the knowledge that has been produced from research translates into improved care and residents' experiences. The authors also describe the challenge of carrying out high quality research in care home settings that is both relevant to this sector and that engages with the people involved including residents, family members, and care home staff. As such, the study was designed to incorporate key stakeholders' (including family members, care home staff, and health care professionals) views, experiences and expertise in the development and refinement of the intervention. Taking this approach provided a deeper understanding of the care home culture meaning that IPOS-Dem was designed for the care home setting. Furthermore, implementation barriers could then be anticipated and potentially overcome during the development stages, and considered in relation to the design of the study. However, care homes are not homogenous and include different types of ownership, funding, size, and resident profiles (1, 177, 178). There is also wide variety in how residential care homes work with health care providers and in leadership styles (178). This study made the attempt to recruit a mix of residential care homes to develop and examine the intervention in different care home setting types and cultures.

(v) **Understanding of components of intervention including acceptability, feasibility** (3). Key features of acceptability and feasibility of measures used in routine care were identified in the literature (Chapter 1) and IPOS-Dem was developed to maximise these. Evaluation of these was conducted throughout the study, and refinements and intervention recommendations made based on the results.

(vi) **Expert consultation with patient and public involvement members, care home staff and health care professionals** (3, 159). Expert consultation with patient and public involvement (PPI) members, care home staff, senior multi-disciplinary health care professionals and academics were conducted at all stages of the study including study design, and development of study materials. Expert consultation was also utilised in the development and refinement of IPOS-Dem.

PPI involvement comprised an older adult mental health and dementia service user and carer advisory group who were consulted on the study design and study material. This group was also consulted on the development of IPOS-Dem and provided feedback on its versions in the process of development. Regular presentations were made to this group of approximately 15-30 service user and carer representatives. Presentations were followed by feedback and discussion.

A PPI member with carer experience also supported the study (Appendix C). Consultation with this individual involved designing and refining the study aim and study design, and improving the clarity and language of the study materials in order to improve readability, relevance and comprehension (179).

Senior palliative care health professionals and academics were consulted on the intervention development. Early collaborations with mental health, palliative care, and general practice health care professionals not directly involved in the study were developed to understand how IPOS-Dem may support and complement existing health and social care structures and processes.

From the time of the approaching care homes, managers and care home staff were consulted on the conduct of the study. During the study set-up and preparation, regular meetings and visits to the care homes took place to discuss the study. Care home staff were invited to share ideas on how the study should be conducted and on the development of IPOS-Dem. The same consultation took place with General Practitioners (GPs), district nurses (DNs) and senior community nurse managers.

(vii) **Mixed methods research** (2, 3, 93, 159). The MRC guidance (2, 3, 93) and MORECare statement (159) both advocate the use of mixed methods in developing and evaluating interventions. A more detailed discussion of the methodological and theoretical considerations of mixed methods research is warranted, and presented in the following section.

4.6 Mixed methods research

The choice of methods must be determined by the study aims and objectives. Qualitative research lends itself to exploring and understanding meaning that participants may ascribe to the phenomenon under study (180). It is well suited to understanding, moving beyond '*how much?'* or '*how many?'* to how and why things happen the way that they do (181). Quantitative methods on the other hand, provide the means for measuring and for testing the relationship between variables (180). Mixed methods research is an approach that combines both qualitative and quantitative forms, but is more than simply collecting and analysing both separately (180). Instead, mixed-methods is an approach that enables research of more complex phenomena, and in health care is well suited to understanding more about interventions and the environment (182). Mixed methods research is therefore useful, for example, when the inclusion of a second method may enhance understanding, such as in an embedded mixed methods design (183).

This study utilised both qualitative and quantitative methods, using qualitative phase to develop IPOS-Dem followed by evaluation utilising an embedded qualitative design. Qualitative data provided an in-depth understanding of the requirements of the IPOS-Dem including content validity (objective 2), comprehension (objective 3), acceptability (objectives 3, 4 and 7), feasibility (objectives 4 and 7), the context and how the mechanisms of action work within the context (objectives 4 and 5), and implementation requirements (objectives 4 and 6) both during the development/pre-implementation and evaluation/post-implementation phases of the study. Quantitative data provided a different level of data about the acceptability (objective 7) and feasibility (objective 7) of the intervention by providing numerical data on IPOS-Dem scores in the evaluation/post-implementation phase. These data were integrated to provide a detailed and enhanced understanding of IPOS-Dem as an intervention in routine care of people with dementia living in residential care homes.

An embedded design uses a traditional qualitative design with an embedded quantitative strand, or vice versa (183). Priority is given to the primary strand while the embedded strand is utilised to answer different questions or study different levels of data relating to the overall study, thus enhancing understanding of the primary strand (180, 183). Data collection and analysis of the embedded strand may occur before or after (sequential), or during (concurrent) the data collection

and analysis of the main design. Unlike many other mixed methods designs, the two types of data are not merged in order to answer the same question. Instead the results from each method may be presented alongside each other to provide composite results of the different research questions or levels of data (180). The data are analysed separately and then used as a means of triangulation at the interpretation of the study (184). In this way, the findings from both the qualitative and quantitative data can be compared to identify areas of convergence, complementarity or discrepancy in order to provide a deeper understanding of the question under study (184-186). This approach is taken by this study in particular, when utilising both types of data in understanding acceptability and feasibility of the intervention (Objective 7).

A challenge of using mixed methods is that it presents and epistemological tension, with qualitative approaches being associated with an interpretive paradigm and quantitative approaches being associated with positivist paradigm; and that these being considered as incompatible and mutually exclusive (187, 188).

4.7 Methodological considerations

4.7.1 Philosophical basis, positioning and reflexivity

Originally developed by Bhaskar (189), critical realism is a philosophy which argues that the world is complex and multi-dimensional, and that powers, structures, and relations may be observable and measurable, but may also remain unobservable until they are triggered in a particular context (190). This means that the mechanism of action of an intervention may be hidden or suppressed until revealed in a particular context (190).

Realists have argued against the methods proposed by the MRC guidance (2, 93), in particular the use of randomised controlled trials (RCTs) in evaluating complex interventions, stating that they fail to understand the mechanisms, and under what conditions and contexts the interventions may work (188). However, subsequent arguments have been made that realist evaluations, with the underpinning philosophy of critical realism, may be well suited to evaluating complex interventions; and that in particular, realist evaluations may be synergistic with RCTs to evaluate how the mechanisms may operate in context, and which mechanisms may promote or inhibit effectiveness (5, 167, 191). The MRC process evaluation guidance draws upon realist evaluation

to determine how context-mechanisms-outcome configurations work together to understand 'what works', 'for whom' and 'under what circumstances' (5). It has also been proposed that realist evaluations may work well with theory of change in understanding the complexity of multiple mechanisms of action within the real world context (95).

The tension of using mixed methods may be resolved by adopting an anti-conflationist view that qualitative and quantitative approaches can be combined if an ontological and epistemological position is maintained (187). Critical realists distinguish between three different modes of reality or ontological domains. These are the empirical (the visible phenomena that can be experienced), the actual (that which occurs whether observed or not), and the real (the underlying structures and mechanisms which may generate the actual phenomena) (187, 189). Critical realists take an anti-conflationist view, and argue that research aims to go beyond positivist goals to generate generalizable laws, or the interpretivist goals to identify the lived experiences of individuals. As such, it is necessary to draw upon qualitative and quantitative approaches depending on the research question and that mixed methods are frequently required and the most suited (187).

Like qualitative research, post-positivist science recognises that research is not value free, and that the researcher brings their experiences, assumptions, and values to the research process (192). Reflexivity is a researcher's internal dialogue and continued self-critique of their own assumptions and values; and the active acknowledgement and explicit recognition of how the subjectivities and position of the researcher may affect the research process and outcomes (192, 193). To enhance and facilitate reflexivity, I maintained a diary throughout the course of the PhD (181). This provided the opportunity to record reflections of formal and informal meetings and discussions with family members, care home staff, and health care professionals; as well as other stakeholders such as palliative care teams. I also recorded reflections following focus groups and interviews, and used the diary as a means to record some of the practical challenges as well as challenges in my own learning and thinking. When analysing the data and interpreting the findings, I was able to use these reflections and discussions with supervisors, to gain a deeper understanding of the data, and how my own assumptions and values may have had an effect on this.

4.8 Study site recruitment

4.8.1 Recruitment of residential care homes

There are known challenges to conducting research in care homes (194). One challenge is recruiting care homes to participate in research, with recruitment being resource-intense (194) and researchers typically required to approach 40% more care homes than they require for the study in order to recruit (195). This study drew upon resources such as NIHR Enabling Research in Care Homes (ENRICH) (194), publications and guidance (196) and previous studies (197) to inform recruitment of care homes.

Eligible residential care homes were those providing care to people aged 65 and over, and larger than 15 beds in order to provide sufficiently large population of residents with dementia. Residential care homes were recruited to provide a mix of dementia-registration (to provide a mix of residents with complex and non-complex symptoms of dementia), funding and ownership types (to provide a mix of organisational management, leadership, priorities and cultures). Residential care homes meeting the eligibility criteria were identified from review of the CQC (1) registration details. Letters of approach were sent to providers of identified residential care homes and followed up with a telephone discussion (Appendix D). If agreement was obtained by the care home providers, the manager of the residential care home was approached and the study discussed and introduced to the manager and care home staff. If the manager and care home staff were in agreement, the residential care home was identified as potentially eligible. Final recruitment was made on the basis of agreement by care home providers, residential care home managers and staff, and obtaining a mix of funding types.

4.9 Ethical considerations and approvals

4.9.1 Ethical approvals

Ethical approval was required from a National Research Ethics Service (NRES) and, for one of the participating care homes, from a care home provider ethics committee. Research governance approvals were required from National Health Service (NHS) Research and Development (R&D) for participating NHS sites, and local authority for recruitment of participants from care homes.

Ethical approval was obtained from the Research Ethics Committee (REC) – London South East, a committee flagged for adults lacking capacity [NRES: 13/LO/1339] (18/11/2013). The REC also approved Site Specific Assessments (SSAs) for each of the participating care homes (Care home A: 24/03/2014, Care home B: 24/03/2014, Care home C: 10/06/2014). NHS approvals were obtained to recruit health care professionals employed by the NHS. As only health care professionals were identified for participation from NHS sites, and no part of the study was conducted within the NHS nor were the NHS sites responsible for the delivery of research procedures, NHS Participant Identification Centre (PIC) assurance was given and full study site approval was not required. Two NHS PIC sites were involved: (i) provided by South London Primary Care R&D Office (R&D reference: 035) for recruitment of GPs to the study (18/12/2013), (ii) provided by South East London R&D for the recruitment of DNs to the study (26/03/2014). A minor amendment regarding the conduct of focus groups was submitted and approved (14/03/2014). A substantial amendment regarding recruitment and informed consent of family members and professionals (care home staff and health care professionals), and adding members of the research team was submitted and approved (17/04/2014). A third amendment (substantial) was submitted to temporarily change the study Chief Investigator (16/12/2014). A final substantial amendment was made and approved in order to amend research questions, study design and methodology, outcome measures used, study exclusion criteria, and recruitment and consent of residents with dementia or cognitive impairment (22/04/2015). The ethics application, substantial amendments, and approvals are included in Appendix E.

As the study settings were care homes, local authority Research Governance Framework (RGF) approval was also required. This process included submission of the *London RGF Alliance Common Proposal Form* to the local authority (Appendix F), and presentation at the local authority research governance board, following which approval was obtained (30/08/2013). All amendments which were submitted to the REC were also submitted to the board and approvals received.

Finally, one of the care home organisations had their own ethics committee. An organisation *Application for Ethics Approval* was submitted. Following review of the application, the ethics group initially decided against supporting the research. However, a response to their concerns was submitted, and the organisation's ethics group then approved the application (07/01/2014).

All amendments were also submitted to the ethics committee and approvals received. The application is included in Appendix G.

4.9.2 Ethical considerations: research with adults who lack capacity

The Mental Capacity Act (MCA) 2005

The MCA defines a person as lacking capacity as follows:

> 'a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain' (173)

In relation to consenting to participate in research, this means that the person being recruited is not able to make an informed decision to consent due to a condition affecting decision-making abilities.

There a five key principles to the MCA (173) as follows:

(i) A person must be assumed to have capacity unless it is otherwise established.

(ii) A person should not be treated as unable to make a decision unless all steps to have been made to assist the decision-making.

(iii) A person should not be treated as unable to make a decision just because an unwise decision is made.

(iv) An act or decision made on behalf of the person who lacks capacity must be done in their best interests.

(v) In making a decision on behalf of a person who lacks capacity, the least restrictive option must be selected.

Assessing mental capacity

According to the MCA (173), a person is unable to make a decision if unable to:

(i) *Understand* the information relevant to the decision.

(ii) *Retain* the information.

(iii) *Use or weigh up* the information to inform the decision.

(iv) *Communicate* the decision, in any way.

A person should be enabled to understand the information in the most appropriate way (including visual aids and simple language) and is not considered to lack capacity if requiring support to understand the information. The information relevant to the decision includes information about the foreseeable consequences of deciding either way or failing to make the decision. Even if a person can only retain the information for a short period, it does not mean that they do not have capacity to make the decision.

The MCA (173) and research requirements

It is a legal requirement that any study that conducts invasive research with people lacking capacity obtains the correct approvals prior to the research commencing (173). Invasive research is any research that would have required informed consent if the participants had capacity to consent (173). Approvals were therefore required from a REC flagged for adults lacking capacity.

The MCA stipulates a number of conditions for research to be conducted in a person lacking capacity:

(i) The research must be conducted into the condition causing impaired capacity, or the treatment thereof.

(ii) The research cannot be carried out as effectively in persons with capacity to consent.

(iii) The research must have potential to benefit without causing disproportionate burden on the person; or provide knowledge of the causes, treatment or care of the same condition.

(iv) If the research does not have the potential to benefit or provide knowledge into the condition, then the risk to the person should be expected to be negligible and the research should not be burdensome of interfere with privacy or freedom of action in any way.

This study addressed these requirements as follows. IPOS-Dem is a measure and it is essential that measures are developed for and tested in the population that they are intended for (106). Furthermore, measures are more valuable if they work along the whole trajectory of the illness (from early stages to death) (124) as this ensures relevance to all people with dementia living in care homes. It would therefore be inappropriate to develop and evaluate the measure in just people with mild cognitive impairment or early stage dementia who retain capacity to consent.

Finally, the purpose of IPOS-Dem is to assess symptoms and concerns in all people with dementia in care homes including and, in particular, those who may have difficulties expressing their wishes and concerns, and may therefore not be able to communicate symptoms and concerns. It was therefore essential to conduct the study incorporating this population in order to understand how using the measure supported their care. It would not have been possible to sufficiently evaluate the measure in a population without dementia or only with those who are able to self-report their symptoms and concerns.

The MCA and recruiting adults who lack capacity

If the above conditions are met, then the MCA (173) states the process of recruiting people who lack capacity to the study. The first step is to identify somebody who is involved in the care of or welfare of the person but not in a professional capacity e.g. family member or friend who is prepared to be consulted about the person's participation in research (personal consultee). If a personal consultee cannot be identified, then a nominated consultee who is prepared to be consulted and is independent from the research project must be identified and consulted on the person's participation in research.

The personal or nominated consultee must be presented with information about the research and asked, based on their knowledge of the person lacking capacity, whether that person would wish to take part in the research.

Recruitment of residents with dementia or cognitive impairment to this study

The study adhered to the MCA (173) in recruiting adults lacking capacity to consent, and a detailed recruitment protocol was developed (Figure 9). This study's recruitment protocol drew upon an earlier study protocol of recruiting adults who lack capacity developed by Scott and colleagues (198). The MORECare statement also informed the recruitment protocol (169).

The first step in recruitment was to advertise the study in care homes. Posters were displayed with my photograph and contact details, as well as details of a coffee morning for residents and family members (including friends) (197, 199) (Appendix H). The coffee mornings were conducted in each care home to share information about the study, and invite residents and family members to ask questions about the study. It also provided the opportunity for residents and family

members to decline participation if they so wished. The coffee mornings enabled the researchers to advertise the study, invite residents and family members to attend, and therefore provided a means of having contact with those interested in hearing about the study. The coffee morning also facilitated the opportunity for researchers to discuss the study with residents, family members and care home staff to gain their perspectives, inputs, and suggestions about the purpose and conduct of the study. This enabled the researchers to, within the requirements of ethical approvals, incorporate participants' suggestions into the study methods. Study materials including participant information sheets were made available at this time. Appendix I includes examples of participant information sheets from each data collection phase of the study.

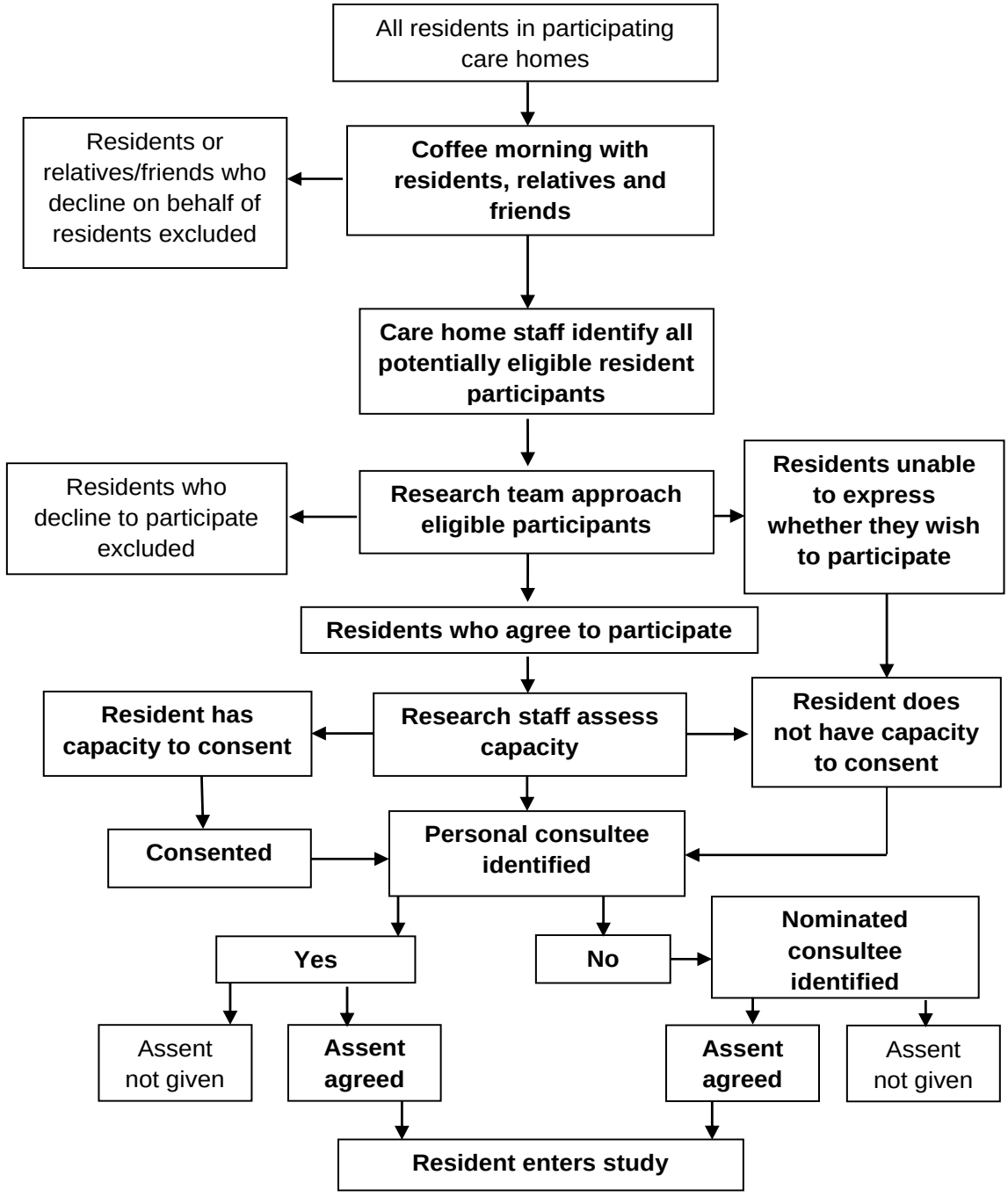


Figure 9 Flow chart of resident recruitment protocol

A meeting was then held with a senior member of the care home staff of each care home to identify residents meeting the inclusion criteria. Inclusion criteria were people aged 65 and over, for whom the care home formed their permanent residence with a documented diagnosis of dementia (any stage) or cognitive impairment. Care was taken to identify eligible residents using the least invasive method i.e. not assessing residents' cognitive abilities. All residents with a

documented diagnosis of dementia were approached to participate in the study. To identify those residents with cognitive impairment, the FAST (32) was used, with residents at stages four to seven being included. Stage four was chosen as the cut-off as it is the mildest stage that does not require a clinical investigation or interview to identify cognitive deficits. This facilitated inclusion of residents with moderate cognitive decline who could be identified by senior care home staff.

Those residents identified as meeting the inclusion criteria by senior care home staff members were introduced to a research nurse and me by care home staff. If the resident was in agreement, one of us met with the resident to discuss the study with the aid of a single side participant information sheet (Appendix I). If the resident comprehended this, it was left with the resident along with a more detailed participant information sheet (Appendix I) to give the opportunity for family members to read about the study and ask questions if needed. If the resident was assessed to have capacity, I returned after one week (or more if requested) to undertake informed consent process. Appendix J includes examples of participant consent forms.

It was anticipated that those residents that had capacity to consent, may lose capacity over the course of the study. The MORECare statement on ethical issues in palliative and EoLC research (169) recommends a 'belt and braces' approach to recruiting people who may lose capacity. In this way, the MCA (173) can be adhered to if participants lose capacity. This study took this approach. As such, advice from a consultee was obtained for all residents who provided informed consent, as well as all residents who were assessed not to have capacity, and did not demonstrate unwillingness or reluctance to participate (169, 173). As such, if a resident lost capacity over the course of the study, they were not withdrawn from the study. Taking this approach meant that the least invasive approach was taken in gaining informed consent as residents were only approached once, rather than at each data collection point.

Personal consultees were identified by care home staff. They were identified based on residents' pre-specified wishes (i.e. if this was a lasting power of attorney in place) or based on the knowledge of care home staff (i.e. a family member of close friend who knows the resident well and visits the resident regularly). Senior care home staff sent a letter of approach to identified potential personal consultees on my behalf. The letter included brief information about the study, and information about the role of the personal consultee. The letter asked the recipient to contact

me if they would like to be consulted. The letter also made explicit that if no contact was received within three weeks, a nominated consultee would be consulted. Two letters were sent to potential personal consultees (Appendix K).

The nominated consultee for this study was a research practitioner from the Clinical Research Network South London (CRN SL) Division 4 – Dementia and Neurodegenerative Diseases (DeNDRoN) speciality. The research practitioner was independent from the study but had expertise in research conduct and implications of resident participation and was therefore well-placed to give advice on participation. The research practitioner used all available information available in order to give advice on participation. This included meeting residents, reviewing care home notes and discussion with care home staff. Personal and nominated consultees signed a consultee declaration form (Appendix J).

4.10 Summary

In this chapter key guidance, frameworks, and legal documents are presented and discussed in relation to how they informed the overall study design, methodology, and conduct. Detailed methods relating to the specific phases of the study are presented in respective subsequent chapters.

4.11 Presentation of detailed methods and results

The following chapters describe the specific methods of the study for the different study components (Figure 5):

Chapter 5 – pre-clinical literature scoping review to develop IPOS-Dem Version 1 (study objective 1)

Chapter 6: publication 2 – qualitative phase to develop IPOS-Dem Versions 2 and 3 (study objectives 2 and 3)

Chapter 7: publication 3 – qualitative and mixed methods phases to conduct pre- and post-implementation evaluation of IPOS-Dem and develop theoretical model (study objectives 4, 5, 6 and 7)

5. Pre-clinical phase: development of IPOS-Dem Version 1

5.1 Introduction

For a measure to have content validity and acceptability (11, 13), it is important that the items are *relevant* and *comprehensive* to the construct being measured (10). This means that the included items must be relevant for the purpose of the measure e.g. to assess symptoms and concerns in routine care, and be *relevant* to the population e.g. people with dementia living in care homes (10). It is also important that the measure is *comprehensive* to ensure that the construct assessed is captured by all the items (10). POS/IPOS was developed as a measure for clinical care and research, and its purpose to assess all domains of palliative care to support patient care is established (87, 158, 200). POS/IPOS was not, however, developed specifically for the care of people with dementia in care homes. It was therefore important the items were assessed for relevance to this population. It was also important that the measure is comprehensive to ensure that all important symptoms and concerns experienced by this population are included.

This chapter details the aim, methods, and results used to inform the development of IPOS-Dem Version 1. In particular, to ascertain the relevance of IPOS items to people with dementia in care homes and to identify key symptoms and concerns that this population may experience to ensure it the comprehensiveness of IPOS-Dem.

This phase was a pre-clinical phase of the MRC guidance (93) drawing upon what is known in the literature to develop the intervention. This phase also draws upon the methods for measure development to ensure that the measure is developed for the purpose it is intended and for the population it is intended. In particular, utilising literature reviewing and expert consultation (10). The experts comprised academics and health care professionals in primary, palliative, and mental health care, and PPI members. They were consulted regarding decisions about inclusion, exclusion and amendments of items.

5.2 Aim and objectives

5.2.1 Aim

To develop IPOS-Dem Version 1 by identifying IPOS items that have less relevance to people with dementia in care homes and identifying additional symptoms and concerns experienced by this population.

5.2.2 Objectives

1. To examine the evidence of content validity of POS/IPOS for people with dementia in care homes.
2. To conduct a scoping review to identify common physical symptoms and emotional and social concerns experienced by people with dementia in care home settings through the course of the illness trajectory.
3. To construct IPOS-Dem Version 1 based on the amendment or removal of less relevant items and identification and addition of important symptoms and concerns experienced by people with dementia in care homes.

5.2.3 Objective 1: to examine the evidence of content validity of POS/IPOS for people with dementia in care homes

A systematic review of studies using POS (156) and review of the literature of POS used with people with dementia in care homes (Chapter 3) identified one study which provided quantitative data on POS item relevance for people with dementia. This study was used to examine the evidence of content validity for use in this population. In particular, items of less relevance to this population were identified for potential amendment or exclusion.

The identified study examined the use of a Dutch-translated staff/health care professional version of POS, completed by physicians or nursing staff for residents in 16 nursing homes (143) in the Netherlands. Eligibility criteria were all residents with a life expectancy of six weeks or less, admitted for long term care. Residents scoring 5-7 on the GDS (31) were categorised as having dementia. The response options *'Unknown'* and *'Not applicable'* were added to questions 1-9, and *'Unknown'* was added to question 10 on the POS.

POS data were reported for 195 residents with dementia whose data could be included for analysis, of a total sample size of 448 of people with and without dementia. Table 6 shows completion rates of each POS item for residents with dementia. The authors concluded that POS is suitable for people with dementia in care homes as POS was successfully completed for a large subgroup with dementia, particularly those in stages 5 and 6 of the GDS (31). Nonetheless, the results indicate that some items require changing to improve the relevance to this population.

Table 6 Completion rates for POS in people with dementia in nursing homes (143)

Item	**Residents with dementia (n=195)**		
Over the past 3 days …	POS item completed (%)	POS item entered as not applicable or unknown	
		Not applicable (%)	Unknown (%)
1. Has the patient been affected by pain?	78.1	17.7	4.2
2. Have other symptoms	75.0	20.8	4.2
3. Have they been feeling anxious or worried about their illness	**40.2**	**40.2**	**19.6**
4.Have any of their family or friends been worried or anxious	89.2	3.6	7.2
5. How much information has been given to the patient/ family/ friends	82.7	16.8	0.5
6. Has the patient been able to share feelings with family/ friends	**40.4**	**52.7**	**6.9**
7. Do you think they have felt life was worth living?	**23.2**	**52.1**	**24.7**
8. Do you think they have felt good about themselves?	**18.3**	**50.8**	**30.9**
9. How much time do you feel has been wasted on appointments relating to healthcare?	67.5	25.3	30.9
10. Have any practical matters resulting from illness been addressed?	50.3	-	49.7

Bold >50% missing indicated as *'Not applicable'* or *'Unknown'*

Implications for this study:

IPOS-Dem was being developed from IPOS, a more recent development of POS. As such, the next step was to map the less relevant POS items identified in the Dutch study (143) against the corresponding IPOS items to identify which IPOS items required amending (Table 7). This was done in consultation with experts including PPI members, health care professionals, and academics. Four items were identified as requiring amendment as more than 50% was rated as either *'Not applicable'* or *'Unknown'*: (i) *'Have they been feeling anxious or worried about their illness?'*, (ii) *'Has the patient been able to share feelings with family/ friends?',* (iii) *'Do you think they have felt life is worth living?',* (iv) *'Do you think they have felt good about themselves?'.*

The first two: (i) *'Have they been feeling anxious or worried about their illness?'*, and (ii) *'Has the patient been able to share feelings with family/ friends?',* had both been changed slightly between the POS and IPOS versions, but were still considered to be less relevant to people with dementia in care homes and were therefore identified for amending. The third, *'Do you think they have felt life was worth living?'* had been replaced by, *'Do you think that s/he felt depressed?'* As

depression is common in people with dementia (33), it was anticipated that this item would have relevance in this population and it was therefore retained for further testing. *'Do you think that they have felt good about themselves?'* had been replaced by to *'Do you think that s/he has felt at peace?'* Assessing existential concerns are an important part of palliative care provision (14), including for people with dementia in care homes (201). This item was therefore retained for further testing in this population. One new IPOS item was identified as potentially having less relevance for people with dementia in care homes: *'Has the patient had as much information as s/he wanted?'* which had replaced, *'How much information has been given to the patient and their family or friends?'* This item was therefore also identified for amending.

Table 7 Original POS and IPOS items, and those identified for amending for IPOS-Dem

Original POS item	**Corresponding IPOS item**	**Items to retain or amend**
Q1. Has the patient been affected by pain?	Q2. How has the patient been affected by each of the following symptoms: Pain	Q2. Retain
Q2. Have other symptoms	Q2. How has the patient been affected by each of the following symptoms: POS-S items	Q2. Retain
Q3. Have they been feeling anxious or worried about their illness	**Q3. Has s/he been feeling anxious or worried about his/her illness or treatment?**	**Q3.To be amended**
Q4.Have any of their family or friends been worried or anxious	Q4. Have any of his/her family or friends been anxious or worried about the patient	Q4. Retain
Q5. How much information has been given to the patient/ family/ friends	**Q8. Has the patient had as much information as s/he wanted?**	**Q8. To be amended**
Q6. Has the patient been able to share feelings with family/ friends	**Q7. Has the patient been able to share how s/he is feeling with his/her family or friends as much as s/he wanted?**	**Q7. To be amended**
Q7. Do you think they have felt life was worth living?	Q5. Do you think that s/he felt depressed?	Q5. Retain
Q8. Do you think they have felt good about themselves?	Q6. Do you think that s/he has felt at peace?	Q6. Retain
Q9. How much time do you feel has been wasted on appointments relating to healthcare?	Not included in IPOS	Not applicable
Q10. Have any practical matters resulting from illness been addressed?	Q9. Have any practical problems resulting from his/her illness been addressed? (such as financial or personal)	Q9. Retain

Items in bold represent those identified for amending

5.2.4 Objective 2: to conduct a scoping review to identify common physical symptoms and emotional and social concerns experienced by people with dementia in care home settings through the course of the illness trajectory

To ensure that IPOS-Dem includes common symptoms and concerns experienced by people with dementia living in care homes, it was important to identify which symptoms and concerns should be added to ensure comprehensiveness.

A scoping review was conducted to identify symptoms and concerns that people with dementia may experience. The aim of the scoping review was therefore to identify physical symptoms, and emotional and social concerns experienced by people with dementia in care homes.

5.2.4.1 Scoping review methods

Search strategy: Ovid MEDLINE in process and other non-indexed citations and Ovid MEDLINE, PsycINFO, and Embase Classic and Embase from inception to 23 December 2013 were searched. A search strategy was developed using a combination of MeSH and key word terms: dementia AND symptom AND long term care AND symptom assessment. The following search strategy was used and supplemented with reference and citation searches using Scopus:

1. Alzheimer Disease/ or Cognition Disorders/ or Dementia/ or Aged/
2. Alzheimer's disease.mp. or Alzheimer Disease/
3. 1 or 2
4. Symptom Assessment/
5. symptom burden.mp.
6. palliative care.mp. or Palliative Care/
7. 4 or 5 or 6
8. Long Term Care/
9. long term care.mp.
10. exp Residential Care Institutions/ or exp Health Care Services/ or exp Nursing Homes/
11. care home.mp.
12. 8 or 9 or 10 or 11
13. 3 and 7 and 12

Eligibility criteria: The population was people with dementia living in care homes. Mixed cognitively impaired and cognitively intact participants were included as long as at least 50% had established cognitive impairment or dementia. When the proportion of population with cognitive impairment was not reported, the study was excluded. All stages of dementia were included. Studies that included multiple settings but reported care home settings separately were included. Acute or general hospitals study settings were excluded as it was expected that patients in these settings would have additional symptoms due to being acutely unwell. However, long-stay/ permanent wards were included.

Studies that aimed to identify the breadth of physical symptoms, and emotional and social concerns were included. Therefore, studies that used a range of methods and measures to identify a wide range of symptoms and concerns were included (e.g. case note review, resident examinations, survey, generic assessment measures). For the same reason, those studies that examined three of fewer symptoms or used dementia-specific measures to identify already-established common symptoms in dementia e.g. Symptom Management at the End of Life in Dementia (125) were excluded. As neuropsychiatric symptoms of dementia including depression, psychosis, aggression and wandering, are already well-established and documented (20, 117), studies that only examined these symptoms were not included. Cause of death studies, co-morbidity studies, and studies that used medication prescription as a proxy for symptoms were all excluded.

Qualitative studies, intervention studies, case studies, theses, reviews and conference abstracts were excluded. Studies were included if they were English language.

Study selection: All titles and abstracts were reviewed and those that did not meet the inclusion criteria were excluded. Full texts of the remaining articles were screened and those meeting the inclusion criteria retained for data extraction. Studies were assessed for risk of bias but not excluded on the basis of quality. Risk of bias was reported on in the interpretation of results.

Data extraction: Data were extracted on study design, study setting, population, symptom measurement methods, symptoms identified/ measured, symptom prevalence. Physical, emotional and social symptoms and concerns were extracted. Diagnoses (such as cancer,

arthritis) were not extracted. An exception to this were psychiatric diagnoses (such as depression and anxiety) in order to capture the prevalence of common neuropsychiatric symptoms in dementia (33). Care processes (such as hygiene and cleanliness) and functional problems such as incontinence, independence in activities of daily living were not extracted as not in construct of measure. Fevers, premortem signs and symptoms, and delirium were not extracted. When different severity (such as mild or moderate pain) or frequency (such as pain more than 5 days a month) symptoms or concerns were reported, the category that encompassed all levels of severity or frequency were extracted. Symptoms identified as present but effectively treated were included in the reported prevalence.

Data analysis: A summary of symptoms and concerns were identified, and prevalence tabulated.

5.2.4.2 Scoping review: results

In total, 1500 papers were identified through the database searches. Following deduplication and abstract screening, 81 full texts were screened with 10 studies meeting the inclusion criteria. Reasons for exclusion were: not care home population (n=8), not dementia population (n=4), not measuring symptom burden (n=15), used a single measure to assess symptoms (n=4), study design e.g. qualitative or review, conference abstract, commentaries or editorials (n=40).
Three additional papers were identified from citation and reference screening resulting in a total of 13 included studies.

Table 8 shows the study details of included studies. Five of the included study populations comprised residents with dementia only (202-206). Three studies analysed a subgroup of residents with dementia separately (18, 207, 208). Four study populations comprised mixed cognitively intact and cognitively impaired residents (209-213) with the proportion of those with cognitive impairment ranging from 59% (212) to 94% (210). Study populations included all stages of dementia or cognitive impairment (208, 209, 212), advanced dementia only (18, 202, 203, 205, 206) and end-stage dementia only (204). Four studies did not specify which stages of dementia were included (207, 210, 211, 213). The populations of the majority of included studies were residents with dementia at the end of life (18, 203-205, 207-212). Of these, four studied those dying with advanced dementia (18, 203-205). Sample sizes ranged from n=17 (204) to n=40,622 (209) with mean age of participants ranging from 76.4 years (Standard Deviation (SD) 13.9) (209)

to 86.5 years (SD 7.8) (208). Methods of data collection comprised review of case/ medical/ nursing records (202-204, 210), after-death interviews e.g. with family members or care home staff (208, 211, 212), and Minimum Data Set (MDS) assessments (18, 205, 209). One study utilised a nursing home physician completed questionnaire (207) and one study utilised multiple methods of data collection including case note reviews, nurse interviews and brief physical examinations (206). One study used a combination of case note reviews and interviews with residents (213). Three studies collected data from family members (208, 211, 212) but only two concerned the family's perspectives on a resident's symptoms and concerns (211, 212). One study reported combined data from family members and care home staff (212) and one analysed agreement between family members and care home staff but only for three symptoms (211). Data collection time periods ranged from 48 hours (210) to 18 months (206). The majority of studies (n=10) (18, 203-205, 207, 208, 210-213) collected data on the last time period of participants' lives, ranging from the last three months (212) to last 48 hours (210) of life.

Table 8 Study details of scoping review papers meeting inclusion criteria

Author, year	Country	Study design	Study setting	Population	Dementia	Dementia severity	Sample size	Mean age years (SD)	Data collection method and time period
Black (2006) (202)	US	Prospective cohort study	3 NHs	Residents	All	Advanced	123	81.5 (7.1)	Baseline data collection: review of medical notes in previous 6 months
Brandt (2005) (207)	the Netherlands	Prospective cohort study	9 purposefully sampled NHs	Residents with life expectancy of ≤6 weeks	Subgroup of mental and behavioural disorders (mostly dementia) which are considered underlying cause of limited life expectancy	Not stated. However, likely advanced dementia as considered to be cause of limited life expectancy	Mental and behavioural subgroup= 156	83.5 (8.1)	Baseline data collection: questionnaire completed by NH physician which included a list of 25 symptoms and open question. Time period not specified.
Buchanan (2002) (209)	US	Analysis of admission assessments	NHs	Residents receiving hospice care	63% cognitive impairment	Mild to advanced	40, 622	76.4 (13.9)	MDS admission assessments completed by trained health care professionals, completed within 14 days of admission to NH
Di Giulio (2008) (203)	Italy	Retrospective study	7 geriatric care homes	Residents who died in previous 12 months	All	Advanced	141	86 (7.7)	Data extracted from clinical records by two independent study nurses on residents' last 30 days of life
Hall (2002) (210)	Canada	Retrospective chart audit	Convenience sample of 5 care homes	Residents who died in 12 month period	51% primary diagnosis of cognitive impairment	Not stated: likely all stages	185	86.2	Audit tool developed by authors based on literature review with common symptoms. Data extracted from resident charts by two auditors for the last 48 hours of life
Hanson (2008) (211)	US	Structured after-death interviews	Stratified random sample of 230 care homes	Residents who had died within specified time period	77% cognitively impaired	Not stated	674 (complete care home staff interviews)	85.4 (9.5)	Structured interviews of family members and care home staff by trained interviewers about the last month of life

Author, year	Country	Study design	Study setting	Population	Dementia	Dementia severity	Sample size	Mean age years (SD)	Data collection method and time period
Lloyd-Williams (1996) (204)	UK	Case note audit	Long-stay psychogeriatric ward	Residents who died with dementia as contributory cause of death	All	End-stage dementia	17	83.2	Case notes, nursing records and medicine charts, for the last two weeks of life
Mitchell (2004a) (18)	US	Retrospective study comparing two cohorts	643 NHs	Residents who died within one year of admission with either advanced dementia or advanced cancer	Subgroup of dementia	Advanced	Subgroup of dementia=160	83.5 (7.1)	MDS completed 120 days within death. Time period of assessment not specified.
Mitchell (2004b) (205)	US	Retrospective cohort study	NHs and community settings	Residents aged 65 years or older with advanced dementia who died within one year of admission to nursing home or home care program	All	Advanced	Subgroup of nursing home residents=273	83.4 (7.1)	MDS completed within 120 days of death. Time period of assessment not specified.
Mitchell (2009) (206)	US	Prospective cohort study	22 NHs	Residents over the age of 60 with advanced dementia	All	Advanced	323	85.3 (7.5)	Quarterly chart reviews, interviews with nurses, and brief physical examinations over 18-month period
Parker (213)	Australia	Prospective observational study	18 care homes	Residents with life expectancy of ≤6 months	64% diagnosis of dementia	Not stated: likely all stages	69	84	Prospective data collection over 10 weeks from case notes and resident interviews
Reynolds (2002) (212)	US	After-death interviews with family members and care home staff	2 NHs	Residents who died	59% assessed as disorientated to time	All stages	80	82	Family members and care home staff interviewed on physical and emotional symptoms in last 3 months of life
Sloane (2008) (208)	US	After-death interviews with family members and care home staff	Stratified sample of 199 residential care homes and 31 NHs	Residents who died	Subgroup of dementia	All stages	Subgroup of dementia=422	86.5 (7.8)	Care home staff interviewed to identify physical and behavioural symptoms in the last month of life

NHs – Nursing homes; MDS- Minimum Data Set; SD – standard deviation; UK: United Kingdom; US: United States

Table 9 shows the symptoms and concerns identified in the included studies. Identified symptoms and concerns ranged from 4 (205) to 18 (209). Identified symptoms and concerns were organised into two main groups: (i) physical symptoms, and (ii) emotional, social, and existential concerns.

(i) Physical symptoms were classified into symptoms or groups of symptoms as follows: pain, shortness of breath, skin problems, swallowing problems, food and fluid intake, vomiting, nausea, constipation, drowsiness or weakness, mouth or dental problems, and other symptoms identified less than three times (oedema, falls, vision problems, bleeding, myoclonus and seizures). Pain and shortness of breath were the most common physical symptoms, identified in 12 out of the 13 studies.

(ii) Emotional, social, and existential concerns were classified as follows: depressed, anxious/agitated, interaction/lonely, and other concerns identified less than three times (hallucinations, restless, activities/ goals, at peace and insomnia). Depressed was the most common of the emotional, social, and existential concerns identified in five studies out of the 13 studies.

Table 9 Symptoms and concerns, and prevalence (%) identified from scoping review studies grouped by physical symptoms, and emotional, social, and existential concerns

Black (2006) (202)	**Brandt (2005) (207)**	**Buchanan (2002) (209)**	**Di Giulio (2008) (203)**	**Hall (2002) (210)**	**Hanson (2007) (211)**	**Lloyd-Williams (1996) (204)**	**Mitchell (2004a) (18)**	**Mitchell (2004b) (205)**	**Mitchell (2009) (206)**	**Parker (2005) (213)**	**Reynolds (2002) (212)**	**Sloane (2008) (208)**
PHYSICAL SYMPTOMS												
Pain												
Pain (63.4)		Pain (71.3)	Pain (26.2)	Pain (44)	Pain (60.7)	Pain (58.8)	Pain (11.5)	Pain (37.1)	Pain (39.1)	Pain (71)	Pain (86)	Pain (57.3)
Shortness of breath												
Respiratory distress (29.3)	Respiratory problems (dyspnoea) (12.2)		Dyspnoea (39.7)	Dyspnoea (62) Noisy breathing (39)	Dyspnoea (49.7)	Shortness of breath (70.6)	Shortness of breath (8.2)	Shortness of breath (12.7)	Dyspnoea (46.0)	Dyspnoea (32) Cough (29)	Dyspnoea (75)	Shortness of breath (46.7)
Skin problems												
Skin problems/ skin disorders (95.1) Pressure ulcers (61.0)	(Worsening) pressure ulcer (16.0)	Other skin problems or lesions (54.9) Pressure ulcers (31.8)	Bed sores (47.5)				Pressure ulcers (14.7)	Pressure ulcers (35.0)	Pressure ulcers (38.7)	Pruritus/ rashes (36)		Skin ulcers (24.5)
Swallowing problems												
Aspiration (15.4)	Difficulty swallowing (12.2)	Chewing problem (27.6) Swallowing problem (23.8)	Choking (0.7)	Dysphagia (28)	Choking (16.0)		Lung aspirations (3.0) Chewing or swallowing problems (45.9)		Aspiration (40.6)	Dysphagia (57)	Choking (not detailed)	

Black (2006) (202)	Brandt (2005) (207)	Buchanan (2002) (209)	Di Giulio (2008) (203)	Hall (2002) (210)	Hanson (2007) (211)	Lloyd-Williams (1996) (204)	Mitchell (2004a) (18)	Mitchell (2004b) (205)	Mitchell (2009) (206)	Parker (2005) (213)	Reynolds (2002) (212)	Sloane (2008) (208)
Food and fluid intake												
Nutrition/ Hydration (85.4)	(Very) little/ no fluid intake (49.4) (Very) little/ no nutritional intake (32.7) Refusal of liquid (7.7) Loss of appetite (1.3)	Leaves about 25+% of food at most meals (65.1) Complains about the taste of many foods (2.0) Regular complaints of hunger (<1.0)			Inadequate food and water intake (73.0) Anorexia (64.4) Episode of dehydration (32.5)					Anorexia (51)	Anorexia (not detailed)	
Weight change												
	Cachexia/ anorexia (17.3)	Loss of weight (28.4) Gain of weight (2.2)			Weight loss (31.5)		Weight loss (26.1)					
Vomiting												
	Vomiting (1.3)		Emesis (26.2)			Vomiting (5.9)				Vomiting (26%)		
Nausea												
	Nausea (1.3) Feeling sick (0.6)				Nausea (7.4)					Nausea (20)	Nausea (not detailed)	
Constipation												
						Constipation (11.8)	Constipation (13.7)			Constipation (75)	Constipation (not detailed)	

Black (2006) (202)	**Brandt (2005) (207)**	**Buchanan (2002) (209)**	**Di Giulio (2008) (203)**	**Hall (2002) (210)**	**Hanson (2007) (211)**	**Lloyd-Williams (1996) (204)**	**Mitchell (2004a) (18)**	**Mitchell (2004b) (205)**	**Mitchell (2009) (206)**	**Parker (2005) (213)**	**Reynolds (2002) (212)**	**Sloane (2008) (208)**
Drowsiness/Weakness												
	Severe stage of somnolence (6.4) Extreme tiredness (3.2) Generalised weakness (28.8)		Drowsiness (19.2)		Less alert (29.2)					Weakness/ fatigue (55)	Fatigue (52)	
Mouth and dental problems												
Dental/ mouth problems (22.8)		Mouth pain (1.9)				Oral thrush (11.8)				Oral discomfort (41)		
Other: oedema, falls, vision problems, weakness, bleeding, myoclonus and seizures												
Oedema (37.4) Falls (48.4) Vision problems (22.8)			Oedema (24.1) Bleeding (14.9) Seizures (2.1)	Myoclonus (16)						Oedema (4) Diarrhoea (39)		
EMOTIONAL, SOCIAL AND EXISTENTIAL CONCERNS												
Psychiatric/ behavioural problems (unspecified) (85.4)	**Depressed**											
		Mood (46.3)					Depressed (9.1)	Depressed (20.5)		Depressed (29)	Very sad or depressed (44)	
	Anxious/ Agitated											
							Anxious (2.8)		Agitated (53.6)	Anxious (51)	Very anxious or agitated (31)	
	Interaction/loneliness											
		(Not) at ease interacting (31.8)									Very lonely (21)	(No) Compassionate daily touch (4.6)

Black (2006) (202)	Brandt (2005) (207)	Buchanan (2002) (209)	Di Giulio (2008) (203)	Hall (2002) (210)	Hanson (2007) (211)	Lloyd-Williams (1996) (204)	Mitchell (2004a) (18)	Mitchell (2004b) (205)	Mitchell (2009) (206)	Parker (2005) (213)	Reynolds (2002) (212)	Sloane (2008) (208)
Other: hallucinations, agitation/restlessness, activities/ goals, at peace and insomnia												
		(Not) at ease in self-initiated activities (70.2) (Not) at eases in planned/ structured activities (78.4) (Does not) establish own goals (84.8) (Does not) accept invitations to group activities (93.8) (Does not) pursue involvement in life of facility (95.6)	Restless (20.6)				Hallucina-tions (2.0)			Insomnia (25) Restless (54)	Insomnia (not detailed)	(Not) at peace (33.3)

Table 9 shows the reported prevalence for each symptom and concern assessed or identified in the included studies. The prevalence of symptoms and concerns varies widely between studies with pain prevalence ranging from 11.5% (18) to 86% (212), shortness of breath prevalence ranging from 8.2% (18) to 75% (212), and depression prevalence ranging from 9.1% (18) to 46.3% (209).

There are a number of reasons for the ranges of prevalence in the studies:

(i) Definition of symptom or concern: Symptoms and concerns were defined according to different criteria. Some studies reported any presence of a symptom (202-204, 207, 210, 212) while others categorised symptoms according to pre-defined frequency or severity (18, 205, 206).

(ii) Method of assessing symptoms or concerns: assessment is challenging in people with advanced dementia, and each assessment method is likely to be subject to some source of bias. In addition, informants have different perspectives and knowledge about symptoms and concerns in people with dementia. Care home staff assess residents based on their close and frequent contact with people with dementia (78). Family members may base assessment on their long-term knowledge of the person, while health care professionals may use clinical examination, discussion with care home staff providing direct care, and observation. One study utilised physical examinations as part of assessment of symptoms (206). Three studies collected MDS assessment data (214-216) which provides guidance on utilising all available methods of assessing residents including communication with and observation of residents, communication with care home staff and health care professionals, communication with family members, and resident records (217). The remaining studies depended on physicians, nursing staff, care home staff, or family members accurately identifying and recording/ reporting symptoms and concerns. Three studies collected data through post-death interviews with family members and care home staff with the potential for recall bias (208, 211, 212).

(iii) Study designs: the scoping review method was designed to identify the breadth of symptoms and concerns experienced by people with dementia in care homes. However, the number and type of symptoms and concerns were limited by the study designs. Some studies assessed only pre-specified symptoms and concerns utilising audit tools (210), questionnaires (207) and interviews (208, 211, 212). This means that the number of symptoms and concerns was limited to only those that had been pre-specified. Other studies, identified all symptoms and concerns identified in case notes (202-204). This method had the potential to identify a wider breadth of symptoms and concerns, although a limitation is whether they had been detected and accurately documented. Data from the MDS were utilised in three studies (18, 205, 209). The MDS (214-216) is a comprehensive assessment of residents, covering multiple domains such as cognition, communication, psychosocial wellbeing, diagnoses, health conditions, nutritional status, skin conditions, activity and medication (217). The comprehensive nature of the MDS did mean that two of the studies examined a wider range of physical symptoms, and emotional, social, and existential concerns (18, 209). The limited number of emotional and social concerns identified from the scoping review is likely to reflect the pre-specified symptoms that the studies aimed to examine and the fact that the majority of included studies aimed to examine physical symptoms only; rather than a true low prevalence of emotional and social concerns in this population (33).

(iv) Period prevalence: the time period that data were collected over impacts on the number of symptoms and concerns identified, with more being identified over longer time periods. The included studies assessed symptoms and concerns over a range of time periods from 48 hours (210) to 18 months (206).

(v) Stages of illness: the different study populations mean that it is likely that symptom prevalence varied. Symptoms and symptom prevalence for populations at the end of life are likely to be different from those not at the end of life, and people with advanced dementia may have different symptoms and symptom prevalence from those with mild to moderate dementia.

5.2.4.3 Scoping review: strengths, limitations and implications for IPOS-Dem development

A systematic approach was used to ensure rigour in identifying the studies, and extracting and reporting the data. However, there are limitations to this scoping review. First, it was conducted to scope the literature rather than as a systematic review. Some eligible studies may therefore not have been identified and included. The search strategy and inclusion criteria resulted in a focus on physical symptoms rather than the full range of physical symptoms, emotional and social concerns that people with dementia may experience; and in study populations predominantly at the end of life, meaning that the symptom burden along the full trajectory of dementia was not fully examined. Extending the search strategy and inclusion criteria to include populations not resident in care homes and studies that examined neuropsychiatric symptoms only may have resulted in a wider range of symptoms and concerns being identified in along the illness trajectory of dementia, but is likely to have resulted in symptoms and concerns less relevant to people with dementia in care homes, and even greater study heterogeneity.

The scoping review was important to identify symptoms and concerns in people with dementia in care homes. Table 10 details the symptoms and concerns identified and maps them to IPOS items resulting in corresponding IPOS-Dem items. Symptoms not already included in IPOS that were common with high prevalence including *'Skin breakdown'*, *'Swallowing problems'* and *'Weight loss'* were added. The IPOS item *'Sore or dry mouth'* was amended to *'Mouth or dental problems'* as both these symptoms were identified in the scoping review. Symptoms that were already included in IPOS were retained for further testing even if they were not identified as common or prevalent in people with dementia in care homes. The less commonly identified symptoms including oedema, falls, vision problems, bleeding, myoclonus and seizures not in IPOS were not included.

It was anticipated that emotional and social concerns had been under-estimated in the scoping review. As such, all of those identified were included in IPOS-Dem (Table 10). *'Do you think that s/he felt depressed?'* was therefore retained and *'Hallucinations'* was added as an item. At this stage the IPOS item, *'Has s/he been feeling anxious or worried his/her*

illness?' was amended to *'Has s/he been feeling anxious or worried?'* Similarly, the less relevant IPOS item, *'Has s/he been able to share how s/he is feeling with his/her family or friends as much as s/he wanted?'* was amended to *'Has s/he been able to interact positively with others?'* to capture *'*Interaction*'.* To capture the concern *'*Activities/ goals', another item, *'Does s/he have the opportunity to engage in enjoyable or pleasurable activities?'* was added.

IPOS-Dem aims to assess symptoms and concerns that are distressing to people with dementia. As it is not intended as a measure of behavioural change or behaviours that challenge, the symptoms and concerns, '*Agitation', 'restlessness'* and *'Insomnia'* were not included in IPOS-Dem Version 1.

Additional items:

Additional emotional and social concerns were identified for inclusion:

(i) A depression screening item, *'Do you think that s/he is still able to enjoy things in life?'* was included. This item has been tested in palliative care populations and had a sensitivity of 79.1% (95% CI 63.5-89.4) and a specificity of 72.6% (95% CI 63.7-80) using a gold standard of diagnosis of major depressive Diagnostic and Statistical Manual of Mental Disorders: Fourth Edition (DSM IV) (218).

(ii) *Delusions* is a common symptom in mild cognitive impairment and dementia, with prevalence estimate of 18% in this population (33). *Delusions* was therefore identified as an additional item for inclusion.

(iii) *'Have any care matters been addressed [hearing aids, foot care, dental, glasses]'.* This was identified as important to address some of the other care concerns that people with dementia in care homes may be likely to experience and that is not sufficiently captured in the IPOS item, *'Have any practical problems resulting from his/her illness been addressed? (such as financial or personal).*

(iv) *'Are priorities and preferences for care reviewed and documented?'* was identified as an important care need for people with dementia in care homes,

and one that could potentially result in fewer hospital admissions and care transitions (219).

Table 10 Identified symptoms and concerns mapped to IPOS items and corresponding IPOS-Dem item

Symptom identified	**Original IPOS item**	**IPOS-Dem item**
Pain	Q2. Pain	Q2. Pain
Shortness of breath/ dyspnoea/ respiratory distress	Q2. Shortness of breath	Q2. Shortness of breath
Skin problems/ skin disorders/Pressure ulcers	**Not included**	**Q2. Skin breakdown**
Aspiration/ difficulty chewing or swallowing/ choking/ dysphagia	**Not included**	**Q2. Swallowing problems**
Poor food and fluid intake/ cachexia/ anorexia/ dehydration/ weight loss	Q2. Poor appetite	Q2. Poor appetite
Weight change	**Not included**	**Q2. Weight loss**
Vomiting	Q2. Vomiting (being sick)	Q2. Vomiting (being sick)
Nausea/ feeling sick	Q2. Nausea (feeling like you are going to be sick)	Q2. Nausea (feeling like you are going to be sick)
Constipation	Q2. Constipation	Q2. Constipation
Somnolence/ Extreme tiredness/ drowsiness/ Less alert/ Fatigue	Q2. Drowsiness	Q2. Drowsiness
Generalised weakness	Q2. Weakness or lack of energy	Q2.Weakness or lack of energy
Dental problems/ mouth problems/ oral thrush	Q2. Sore or dry mouth	**Q2. Mouth or dental problems**
Oedema	**Not included**	Not included
Falls	Q2. Poor mobility	Q2. Poor mobility
Vision problems	**Not included**	Not included
Bleeding	**Not included**	Not included
Myoclonus	**Not included**	Not included
Seizures	**Not included**	Not included
Mood/ very sad/ depressed	Q5. Do you think that s/he felt depressed?	Q5. Do you think that s/he felt depressed?
Anxiety/ very anxious or agitated	**Q3. Has s/he been feeling anxious or worried about his/her illness or treatment?**	**Q3. Has s/he been feeling anxious or worried?**
Hallucinations	**Not included**	**Q2. Hallucinations**
Restlessness	**Not included**	Not included
At ease interacting/ very lonely/ compassionate touch	**Q7. Has s/he been able to share how s/he is feeling with his/her family or friends as much as s/he wanted?**	**Q7. Has s/he been able to interact positively with others?**
At ease in self-initiated activities At eases in planned/ structured activities Establishes own goals Accepts group activities Pursues involvement in life of facility	**Not included**	**Q9. Does s/he have the opportunity to engage in enjoyable or pleasurable activities?**
Peace	Q6. Do you think that s/he has felt at peace?	Q6. Do you think that s/he has felt at peace?
Insomnia	**Not included**	Not included

Amendments of items of less relevance:

The less relevant IPOS item *'Has the patient had as much information as s/he wanted?'* was changed to *'Has his/her family had as much information as wanted?'* to reflect the family members' requirement for information (48, 220, 221).

Language:

To reflect that the care home setting is not a clinical one, the term *'patient'* in IPOS was changed to *'person'.*

5.3 Construction of IPOS-Dem Version 1

Table 11 shows the amendments made to IPOS to form IPOS-Dem Version 1 based on the identification of less relevant items, the scoping review and expert consultation (Appendix O).

Table 11 Original IPOS items, required amendments and corresponding IPOS-Dem items

Original POS/POS-S/IPOS item	**Amendments**	**IPOS-Dem Version 1**
Q1.What has been the patient's main problems over the past week?	None	Q1. What have been the person's main problems over the past week?
Q2. How has the patient been affected by each of the following symptoms over the past week:	**Replace term 'patient' with 'person'**	Q2. How has the person been affected by each of the following symptoms over the past week?
Q2. Pain	None	Q2. Pain
Q2. Shortness of breath	None	Q2.Shortness of breath
Q2. Weakness or lack of energy	None	Q2.Weakness or lack of energy
Q2. Nausea (feeling like you are going to be sick)	None	Q2. Nausea (feeling like you are going to be sick)
Q2. Vomiting (being sick)	None	Q2. Being sick
Q2. Poor appetite	None	Q2. Poor appetite
Q2. Constipation	None	Q2. Constipation
Q2. Sore or dry mouth	**Include dental problems**	**Q2. Mouth or dental problems**
Q2. Drowsiness	None	Q2. Drowsiness
Q2. Poor mobility	None	Q2. Poor mobility
	Include swallowing problems	**Q2. Swallowing problems**
	Include skin breakdown	**Q2. Skin breakdown**
	Include delusions	**Q2. Delusions**
	Include hallucinations	**Q2. Hallucinations**
Q2. Any other symptoms	None	Q2. Any other symptoms
Q3. Has s/he been feeling anxious or worried about his/her illness or treatment?	**Amend to anxious or worried**	**Q3. Has s/he been feeling anxious or worried**
Q4. Have any of his/her family or friends been anxious or worried about the patient?	None	Q4. Have any of his/her family been anxious or worried about the **person**?
Q5. Do you think that s/he felt depressed?	None	Q5. Do you think that s/he felt depressed?
	Include depression screening item	**Q6. Do you think that s/he is still able to enjoy things in life?**
Q6. Do you think s/he has felt at peace?	None	Q6. Do you think that s/he felt at peace?
Q7. Has the patient been able to share how s/he is feeling with his/her family or friends as much as s/he wanted?	**Amend to interaction**	**Q7. Has s/he been able to interact positively with others?**
Q8. Has the patient had as much information as s/he wanted?	**Amend to family information**	**Q8. Has his/her family had as much information as wanted?**
	Include activities	**Q9. Does s/he have the opportunity to engage in enjoyable or pleasurable activities?**
Q9. Have any practical problems resulting from his/her illness being addressed? (such as financial or personal)	**Amend to reflect care home setting**	Q10. Have any practical matters been addressed [such as financial or personal]
	Include care matters to incorporate other concerns such as vision or hearing problems	**Q10. Have any care matters been addressed [hearing aids, foot care, dental, glasses]**
	Include priorities and preferences for care	**Q11. Are priorities and preferences for care reviewed and documented?**

5.4 Summary and next steps

This chapter presents the methods and results used to develop IPOS-Dem Version 1. The objectives were to identify items on IPOS that may be less relevant to people with dementia in care homes, and identify additional items to ensure that IPOS-Dem is comprehensive and therefore includes all important symptoms and concerns that people with dementia and multi-morbidities living in care homes may experience. IPOS-Dem Version 1 is presented in Appendix O, ready for further development, testing and refining in the next phase of this study, reported in Chapter 6: publication 2.

6. Development/pre-implementation qualitative phase: development of IPOS-Dem Versions 2 and 3 [PUBLICATION 2]

This chapter presents findings from the **development** phase qualitative study addressing the study objectives two and three, which are presented again for convenience:

2. To explore the content validity of IPOS-Dem Version 1 to identify additional relevant symptoms and concerns, and redundant items, and refine the measure resulting in IPOS-Dem Version 2.
3. To determine the acceptability and ease of comprehension of IPOS-Dem Version 2 and its manual to care home staff and make necessary refinements based on the results, resulting in IPOS-Dem Version 3 ready for evaluation phase.

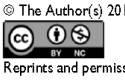
6.1 Development of IPOS-Dem manual

A manual was developed to support care home staff to use IPOS-Dem in routine care for people with dementia. This was developed from and informed by the theoretical model and from the exploration of context, mechanisms of action, and implementation requirements during the development/pre-implementation phase focus groups and interviews presented in the next chapter. More detailed presentation of overall themes and subthemes informing the manual development are presented in Appendix N.

Original Article

PALLIATIVE MEDICINE

Palliative Medicine
2017, Vol. 31(7) 651–660


Reprints and permissions:
sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/0269216316675096
journals.sagepub.com/home/pmj
SAGE

Development of a caregiver-reported measure to support systematic assessment of people with dementia in long-term care: The Integrated Palliative care Outcome Scale for Dementia

Clare Ellis-Smith, Catherine J Evans, Fliss EM Murtagh, Lesley A Henson, Alice M Firth, Irene J Higginson and Barbara A Daveson; on behalf of BuildCARE

Abstract

Background: Symptom burden is common for long-term care residents with dementia which if untreated compromises quality of life. Measurement tools can support assessment of symptoms and problems but are not widely used in long-term care settings. We developed the Integrated Palliative care Outcome Scale for Dementia derived from the Palliative care Outcome Scale, Palliative care Outcome Scale–Symptom and Integrated Palliative care Outcome Scale.

Aim: To examine the content validity, acceptability and comprehension of Integrated Palliative care Outcome Scale for Dementia for routine use in long-term care settings for people with dementia and to refine Integrated Palliative care Outcome Scale for Dementia.

Design: A multi-method qualitative study consisting of focus groups, semi-structured interviews and cognitive interviews.

Setting/participants: Three residential long-term care settings in London, UK. Focus group and semi-structured interview participants included caregiver staff, family, general practitioners and district nurses. Caregiver staff were sampled purposively for cognitive interviews.

Results: A total of 26 respondents participated in the focus groups ($n=21$) or semi-structured interviews ($n=5$) and 10 caregiver staff completed cognitive interviews. Additional symptoms and problems included agitation, wandering, sleep problems, communication problems and diarrhoea. Refinements or lay terms were required to improve comprehension and consistency of item response for nausea, drowsiness, delusions/hallucinations, agitation, loss of interest, communication problems and interaction. A video presentation was required to support comprehension of instructions and assessment of verbally compromised residents.

Conclusion: Integrated Palliative care Outcome Scale for Dementia is a comprehensive and acceptable caregiver-reported measure to detect symptoms and problems in dementia. It is suitable for caregiver staff without professional training as it has been refined and tailored to maximise caregiver expertise, ready for further psychometric testing.

Keywords

Dementia, long-term care, caregivers, symptom assessment, palliative care, qualitative research, outcome assessment

What is already known about this topic?

- Long-term care residents with dementia have high comorbidity and symptom burden, which may be under-detected and under-treated resulting in reduced quality of life.
- Caregiver staff in long-term care settings are well placed to detect symptoms and problems due to high resident contact and knowledge of residents.

Department of Palliative Care, Policy & Rehabilitation, Cicely Saunders Institute, King's College London, London, UK

Corresponding author:
Clare Ellis-Smith, Department of Palliative Care, Policy & Rehabilitation, Cicely Saunders Institute, King's College London, Bessemer Road, London SE5 9PJ, UK.
Email: alexandra.c.ellis-smith@kcl.ac.uk

- Measures used in routine care can support systematic assessment of symptoms and problems but are not widely used by caregiver staff working in long-term care settings.

What this paper adds?

- This paper reports the development and refinement of a comprehensive caregiver-reported measure to support assessment of symptoms and problems for long-term care residents with dementia: the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem).
- The requirements of palliative care measures used by staff without a professional qualification are identified, including the importance of lay terms, and a video presentation on the purpose of the measure and instructions.

Implications for practice, theory or policy

- IPOS-Dem is developed and refined and fills a gap in comprehensive assessment of long-term care residents with dementia by caregiver staff.
- Our study proved essential in improving content validity, and ensuring acceptability and comprehension for caregiver staff with consideration of the long-term care setting, and caregiver remit and expertise.
- IPOS-Dem and its resources are freely available on the Palliative care Outcome Scale (POS) website: http://pos-pal.org/maix/.

Background

Residents with dementia in long-term care settings commonly have high levels of comorbidity,[1] resulting in symptom burden throughout the disease trajectory.[2,3] Symptoms may be undetected and untreated due to declining verbal communication resulting in distress, behavioural changes[4] and reduced quality of life. Caregiver staff in long-term care are well placed to detect symptoms and problems due to frequent contact.[5] However, the majority do not hold a clinical qualification (e.g. nursing), meaning assessment relies on knowledge of a resident, observations and experience.[6,7]

Measures are advocated for use in clinical care to support assessment and monitoring of symptoms and improve access to treatment.[8] They must be valid and reliable, relevant and applicable to the population and setting, brief and easy to use with minimal training.[9] In long-term care, they should be suited to caregiver staff whose assessment is based on knowledge and observation of residents, rather than clinical expertise. However, a recent systematic review demonstrated a paucity of psychometrically sound multi-symptom assessment measures for residents with dementia in this setting.[10]

Based on this systematic review,[10] we identified and selected a validated measure used internationally in routine clinical care to assess and monitor symptoms and problems, the Palliative care Outcome Scale (POS).[11,12] Furthermore, POS has been used in multiple settings and patient groups[12] including long-term care settings in residents with dementia and found useful in identifying palliative care concerns by physicians and nurses.[13] However, the proportion of missing scores for some items ($\leqslant$60%)[13] suggest that POS requires adaptation for this population and setting. In addition, acceptability to unqualified caregiver staff is uncertain.

The work on POS in dementia is preceded by several recent developments in the POS family of measures. In particular, a new Integrated Palliative care Outcome Scale (IPOS) is developed which integrates the core POS with the main symptom module. IPOS encompasses common symptoms and concerns experienced by patients and their families[14] and was developed to meet professionals' requirement for a broader multidimensional measure.[15] Alongside this development, a scoping review[10] identified dementia-related symptoms which might need to be added to IPOS in dementia.[10,16] Consequently, IPOS-Dem was developed to include IPOS plus additional dementia symptoms.[16] In this study, we aimed to determine the content validity, acceptability and comprehension of the draft IPOS-Dem in long-term care settings for people with dementia and to refine IPOS-Dem and instructions based on the results.

Methods

Study design

A two-phase multi-method qualitative study was conducted consisting of (1) focus groups and semi-structured interviews, followed by (2) two rounds of cognitive interviews. Measure refinements were made following phase 1 and after each round of cognitive interviews. Expert consultation with service users and carers, and academics and clinicians from palliative care, primary care and mental

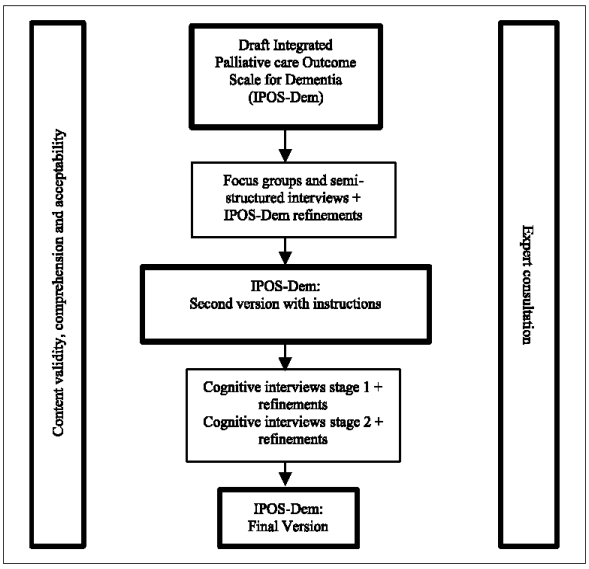


Figure 1. Stages of study.

health was conducted to inform study planning, development of participant information sheet and topic guides, and to refine IPOS-Dem based on study findings (Figure 1).

Setting

Three residential long-term care settings in a London borough, UK. In the United Kingdom, residential care homes, unlike nursing homes, are not required to be staffed by qualified nurses. Each setting was registered to provide care to people aged 65 years and over. Settings were selected based on mix of funding types, ownership and dementia registration.[17] Setting sizes ranged from 26 to 33 beds.

Participant recruitment

Recruitment strategies included formal and informal meetings with managers and caregiver staff to discuss the study. To engage family (including friends), we placed posters in participating settings and held coffee mornings to introduce the study (C.E.S./C.P. (acknowledged)).[18] Family members interested in participating gave their contact details to the research team. We identified general practitioner (GP) practices and district nurse teams working with participating settings and invited professionals to participate.

Participants

Participants for the focus groups/semi-structured interviews comprised caregiver staff, GPs, district nurses and family. All caregiver staff within participating settings were eligible. Eligible health care professionals were GPs and district nurses with responsibility for residents in participating care homes. Family were eligible if 18 years or over, English-speaking and able to provide informed consent. All interested and eligible health care professionals and family members were invited to participate. Caregiver staff were sampled to ensure variation of seniority and roles.

The participants in the cognitive interviews comprised caregiver staff with responsibility for resident record-keeping. Participants were sampled to allow for variation in experience and first language (English/not English). Language was considered important in testing comprehension in a culturally diverse workforce where 19% originate from other countries.[19]

Measure

The draft IPOS-Dem has 28 items. Apart from the first which is unscored, each item is rated on a 5-point scale (not at all (0), slightly (1), moderately (2), severely (3) or overwhelmingly (4) for symptoms; or not all (0), occasionally (1), sometimes (2), most of the time (3), always (4) for other problems). There is an additional option of 'cannot assess' for all items.

Data collection

Focus groups and semi-structured interviews were conducted to examine content validity. Focus groups were

chosen to bring together participant views and enable data to be gained from interactions.[20] Separate professional and family focus groups were planned at each setting. The topic guide included a PowerPoint[21] presentation on the purpose of the assessment measure and questions on (1) the relevance and importance of the items; (2) measure length, that is, number of items; and (3) important missing symptoms or problems.

Cognitive interviews with caregiver staff were conducted to further examine content validity and comprehension and acceptability of IPOS-Dem with instructions[22] and to refine the measure.[14] The interviews were undertaken in two rounds with revisions in round one tested in round two.[23] A sample size of 10 interviews (5 in each round) was expected to provide data saturation.[14,22,23] Participants were asked to complete IPOS-Dem on a resident they know well using 'think-aloud' technique. Concurrent verbal probing was employed to further elicit problems.[24] The topic guide was informed by Tourangeau's[25] model of the survey response process which proposes four cognitive steps involved in responding to surveys (comprehension, recall, judgement and response) and likely cognitive errors. Probes were developed for each of the model's response options. The topic guide also included questions on item relevance, missing items and ease of use. Topic guides were piloted and refined prior to data collection.

All focus groups and interviews were recorded and conducted by a female PhD training fellow, C.E.S. (BSc, MSc), with a clinical background (Occupational Therapy). A focus group observer (C.P./L.A.H.) was present to record field notes and to support participants if required.

Data analysis

Recordings of the focus groups and semi-structured interviews were transcribed verbatim and analysed using directed content analysis.[26] Transcripts were analysed according to pre-determined codes informed by relevance and importance of the items, measure length and missing items. Subcategories were created during analysis and additional codes were created for text relevant to the research question that could not be coded into existing codes.[26] Nvivo 10[27] aided data management, retrieval and analysis.

Cognitive interviews were analysed directly from the recordings into Microsoft Excel[21] using directed content analysis.[22,26,28] A matrix based on Tourengeau's model was developed for analysis with an informant-by-item display.[29] To synthesise the results across participants, a second Microsoft Excel[21] matrix was developed. In this matrix, each item was cross-tabulated with domains of Tourengeau's model. Verbatim quotes were used to illustrate findings[30] and maintained during synthesis.

All analysis was conducted by one researcher (C.E.S.). Regular research supervision (B.A.D./C.J.E.) ensured logical, comprehensive analysis and accurate representation of findings and enhanced reflexivity.

Ethics

Approval was gained from the National Research Ethics Service Committee – London South East (NRES: 13/LO/1339). Site-specific, local authority research governance and setting approvals were obtained. Information sheets were given to all participants at least 24 h before recruitment and written informed consent obtained from all participants (C.E.S./C.P./L.A.H.).

The reporting of the study is in line with the consolidated criteria for reporting qualitative research (COREQ) guidelines.[31]

Results

Focus groups and semi-structured interviews

Four focus groups and three semi-structured interviews were conducted with 26 participants (Table 1). Four GPs were approached, three participated, one declined due to workload reasons. Three district nurses were approached, and one was unable to attend due to prior work commitments. All caregiver staff in the long-term care settings who were approached and able to attend participated ($n=15$). A total of 10 family members expressed interest in participating. Six were recruited. Reasons for non-participation comprised time commitments ($n=1$), non-contactable ($n=1$) and did not arrive ($n=2$). All focus groups/interviews were conducted in the study settings.

The data from focus groups and semi-structured interviews on content validity formed four main themes: value of detailed assessment, dementia-staging items, measurement length and problematic items.

The value of a detailed assessment. Participants overwhelmingly expressed the value of having more items ensuring detailed assessment of residents at the cost of brevity:

> No, I think the more the better because then you're gonna get a more accurate picture of someone's health. (Caregiver staff C1005)

Respondents shared that a detailed assessment ensures all potential symptoms and problems are considered:

> I think that's a good idea and might have things that we wouldn't necessarily think about or get forgotten about because somebody with dementia isn't going to say my glasses aren't very good and I can't see very well and that's why I keep bumping into things and falling so yeah that's useful. (GP A1002)

The usefulness and relevance of functional (e.g. communication difficulties) and behavioural (e.g. agitation)

Table 1. Demographic details of focus group/semi-structured interview participants.

Professional participants ($n=20$)		
Method of data collection	Focus groups (3)	18
	Interviews (1)	2
Sex	Male	2
	Female	18
Years of experience	Mean	10.3
	Median	7.0
	Range	1–29
Profession	Caregiver: manager	3
	Caregiver: team leader/ senior carer	3
	Caregiver: care assistant	7
	Caregiver: activities coordinator	2
	GP	3
	District nurse	2
Ethnicity	White British	8
	White Irish	1
	Indian	1
	Black Caribbean	4
	Black African	5
	Black British	1
Care home	Care home A	7
	Care home B	6
	Care home C	7
Family/friend participants ($n=6$)		
Method of data collection	Focus groups ($n=1$)	3
	Semi-structured interviews ($n=2$)	3
Age	Mean	60.5
	Median	61.0
	Range	53–68
Sex	Male	1
	Female	5
Relationship to resident	Daughter	4
	Son	1
	Friend	1
Care home	Care home A	2
	Care home B	3
	Care home C	1

GP: general practitioner.

concerns with the importance of assessing symptoms or problems that may cause distress was discussed:

> I think sometimes I might be having a conversation with a resident and it's like I ask them something or they want to talk about something and it's definitely there but it's so frustrating because it won't you know, they can't actually say it. (Caregiver staff B1003)

> Like [resident], she wants to say something but the words and suddenly just goes off and can't remember … (Caregiver staff B1006)

> She's angry at herself really. (Caregiver staff B1003)

> … and then she's complaining like ohh I don't know and the words are not coming out and then she's frustrated. (Caregiver staff B1006)

Items to inform dementia staging. There was a lack of consensus regarding the addition of items to inform assessment of dementia staging (e.g. continence). Some participants stated that this is useful to inform assessment while others reported that this would detract from the assessment and risk making assumptions about the resident:

> I think there's a well-established staging system but I think if we get hung up on stage, not recognising that you may be moving across stages if there's an acute physical or emotional event going on. (GP B1004)

Versus

> … if you know at their baseline they were urinating okay and then you know 2 months later they were urinating more often, then hopefully the process will sound okay and there's unlikely to be a major deterioration but there might be more of an infection aspect. (GP A1005)

Measure length. Participants did not identify items for removal from the measure. In the interests of brevity, participants considered combining items including nausea and vomiting, hallucinations and delusions, mouth and dental problems, and enjoyment and engagement in activities:

> … and I think there's a possibility that, I mean I'm not, I don't, I'm not sufficiently qualified to know what the difference between a delusion and a hallucination is, um so I think some things like that could possibly be combined, so whether you put delusions and hallucinations as the same thing and whether you put mouth and dental problems and skin breakdown, all of this all in one category. (Family B1008)

Potentially problematic items. Items were identified as problematic for two reasons: lack of relevance (practical problems) and challenging for caregiver staff to assess or respond to (hallucinations and delusions, practical problems, family information):

> this might be a silly question but what's the difference between a delusion and a hallucination? (Caregiver staff C1003)

and

> I've also had slight problems in that when I want information it's not readily available. (Family C1008)

IPOS-Dem version 2. The results informed refinements of IPOS-Dem and a second version was developed (Table 2). Version 2 included five additional items (wandering, sleep

Table 2. Original IPOS items and IPOS-Dem items resulting from each study phase.

Original POS/POS-S/IPOS item	Draft IPOS-Dem item	Second version IPOS-Dem item	Final IPOS-Dem item
Three main problems	Three main problems	Three main problems	Three main problems
Pain	Pain	Pain	Pain
Shortness of breath	Shortness of breath	Shortness of breath	Shortness of breath
Weakness or lack of energy	Weakness or lack of energy	Weakness or lack of energy	Weakness or lack of energy
Nausea (feeling like you are going to be sick)	Nausea (feeling like you are going to be sick)	Nausea (feeling like you are going to be sick)	Nausea (feeling like being sick/ vomiting)
Vomiting (being sick)	Vomiting (being sick)	Vomiting (being sick)	Vomiting (being sick)
Poor appetite	Poor appetite	Poor appetite	Poor appetite
Constipation	Constipation	Constipation	Constipation
Sore or dry mouth	**Mouth or dental problems**	**Dental problems**	**Dental problems or problems with dentures**
		Sore or dry mouth	Sore or dry mouth
Drowsiness	Drowsiness	Drowsiness	**Drowsiness (sleepiness)**
Poor mobility	Poor mobility	Poor mobility	**Poor mobility (trouble walking, cannot leave bed, falling)**
	Swallowing problems	Swallowing problems	**Swallowing problems (e.g. chokes, inhales food or drink, holds food in mouth)**
	Skin breakdown	Skin breakdown	**Skin breakdown (redness, skin tearing, pressure damage)**
		Distressed by problems communicating	**Difficulty communicating**
		Poor sleep quality	**Sleeping problems**
		Loose bowels	**Diarrhoea**
	Hallucinations	Hallucinations	**Hallucinations (seeing or hearing things not present) and/or delusions (fixed false beliefs)**
	Delusions	Delusions	
		Agitation	**Agitation (restless, irritable, aggressive)**
		Wandering	**Wandering (as a result of distress or putting person at risk)**
Any other symptoms	Any other symptoms	Any other symptoms	Any other symptoms
Anxious or worried about his or her illness or treatment	**Anxious or worried**	Anxious or worried	Anxious or worried
Family or friends been anxious or worried	Family or friends been anxious or worried	Family or friends been anxious or worried	Family or friends been anxious or worried
Depressed	Depressed	Depressed	Depressed
	Enjoyment	**Loss of interest**	Loss of interest
At peace	At peace	At peace	At peace
Share feelings with family or friends	**Interact with others**	Interact with others	**Interact with others (staff, family, residents)**
	Engage in activities	Engage in activities	**Enjoy activities**
Patient information	Family information	Family information	Family information
Practical problems resulting from illness been addressed (such as financial or personal)	Practical problems resulting from illness been addressed (such as financial or personal)	Practical problems resulting from illness been addressed (such as financial or personal)	**Practical problems been addressed, for example, hearing aids, foot care, glasses, diet**
	Care matters been addressed	Care matters been addressed	
	Priorities and preferences	Priorities and preferences	
	Weight loss	Weight loss	**Weight loss: weight and date taken**

POS: Palliative care Outcome Scale; POS-S: Palliative care Outcome Scale–Symptom; IPOS: Integrated Palliative care Outcome Scale; IPOS-Dem: Integrated Palliative care Outcome Scale for Dementia.
Items in bold indicate a change from previous study phase.

problems, communication difficulties, loose bowels and agitation). To retain the construct of IPOS-Dem as a measure to assess symptoms and problems and, in keeping with the responses of the majority of participants, dementia staging items were not added. Items identified as potentially problematic were retained for further testing.

Cognitive interviews

In all, 10 out of 11 caregivers approached, participated in cognitive interviews (reason for declining not given). Caregivers were all female with experience working in long-term care settings ranging from 4 to 24 years (⩽10 years: $n=3$, 11–20 years: $n=4$, >20: $n=3$). Four participants reported English as their first language, two reported mixed first language and three reported English as not their first language. Seniority ranged from deputy manager ($n=1$), team leader ($n=1$), senior health care assistant ($n=2$) and health care assistant ($n=6$). Length of the interviews ranged from 86 to 119 min.

Comprehension. Comprehension problems for nine items included 'nausea (feeling like you are going to be sick)',

> feeling like you are going to be sick, like sneezing maybe. (Caregiver staff B2001)

drowsiness, delusions, hallucinations, agitation, anxiety, 'experienced a loss of interest in things or activities s/he would normally enjoy?',[32] 'has s/he become distressed by problems with communication?' and 'Has s/he been able to interact positively with others?' Problems in reading comprehension of the instruction manual resulted in challenges understanding the purpose of the measure and measure completion.

Recall. Participants reported few recall problems in assessment of residents over the previous week. Challenges to recall occurred when the resident symptoms had changed over the past week:

> I had to put a little bit more thought into it, thinking back to the last week, because she does change. (Caregiver staff B2002)

Recall problems also occurred when caregiver staff had not recently worked with residents. In this instance, staff reported that they would obtain the information from colleagues and case notes.

Judgement. Participants demonstrated and reported making their assessment using various methods including observations of the resident,

> You can see when she is walking, she is limping, you can see. (Caregiver staff B2001, discussing assessment of pain)

speaking to the resident, reading care plans, and handovers or discussions with colleagues. Caregivers reported few problems in judgement, however, at times there were challenges to confidently assessing symptoms in residents with compromised verbal communication:

> Can't be 100% because I am not that person. So and that person has dementia and can't express feelings so could be in pain that I don't know about. (Caregiver staff B2002)

and challenges in differentiating between symptoms:

> I can't just judge … that she is depressed, I can't say that … if she hasn't got any pain, and she's been like that, I think we'd think of that [depressed]. (Caregiver staff A2004)

Some items (e.g. dental problems, mobility) required further descriptions to ensure consistency in how respondents assess problems:

> This person wears dentures so I don't think there is an issue. (Caregiver staff B2003)

Consistent with phase two, delusions and hallucinations remained challenging with some participants demonstrating problems in discerning between the two. Similarly, respondents reported continued problems with 'practical problems resulting from illness such as financial and personal' due to limited relevance to this setting. Caregiver remit and knowledge resulted in problems with 'priorities and preferences'.

Response. Few problems were identified in selecting response options. Problems in consistency in selecting severity options for some items (e.g. mobility) were resolved through the addition of item descriptors. Some participants had problems identifying and articulating free text responses.

Layout, acceptability, missing or redundant items. Problems to layout included item ordering (e.g. 'at peace' following sleep resulted in misinterpretation of 'peace' item):

> is that concerning going to bed? Feeling at peace in bed or is that in general? (Caregiver staff B2002)

Layout problems resulted in error in scoring severity. No additional items were identified for inclusion and no redundant items were identified.

Final IPOS-Dem. The majority of comprehension problems were resolved with simple descriptors or amendments using lay terms, for example, 'drowsiness (sleepiness)'. An exception to this was the term 'diarrhoea' as the addition of 'loose bowels' resulted in ambiguity. Changes to layout improved clarity. A video presentation of the

instruction manual was developed. IPOS-Dem scoring was retained.

Discussion

Our study shows that the majority of original IPOS items are relevant to comprehensive assessment of people with dementia. However, this population have additional symptoms and problems that must be included to ensure content validity. We found caregiver staff were able to assess residents as part of routine care using a range of methods. Provision of lay terms and item descriptors improved comprehension and consistency in interpreting and responding to items. These results are important given the lack of a brief psychometrically sound multi-symptom assessment measure for dementia in this setting[10] and the risk of symptoms being under-detected and therefore under-treated.

There is international agreement that palliative care can benefit people with dementia and the requirement for optimal treatment of symptoms.[33] Our findings help deliver this through the provision of data on a new measure for this population. In the long-term care sector, particularly settings with no onsite nursing, caregiver staff need to be able to detect symptoms and problems, recognise health care need, and access it for residents.[34] Novel solutions to assessment technologies are required given the requirement for integrative work between social and health care providers.[35] Our study is one of the first to systematically examine and modify an established palliative care measure,[11] for residents with dementia. We have shown that the measure required adaptation to reflect common symptom and problems, the long-term care context, and caregiver factors.

Our findings demonstrate that assessment measures can be used by generalist unqualified staff in social care settings. This is important as caregiver staff are frequently in the best position to detect symptoms and problems due to regular contact with residents.[5] Nonetheless, important adaptations are required. Caregiver staff providing personal care are not usually professionally qualified[19] and English is not the first language for many.[19] English literacy, particularly of medical terms, may therefore present challenges to comprehension. Consequently, we found it essential to provide lay terms. These aided comprehension and improved consistency in interpreting and responding to items. Similar findings are reported in a study in Germany, where explanations were required to improve comprehension in non-native speakers.[36] A video presentation instructing the use of IPOS-Dem to support assessment in verbally compromised residents proved necessary to support comprehension.

The final version of IPOS-Dem is a comprehensive measure of symptoms and problems experienced by people with dementia in long-term care settings with materials to support use. Measures used in dementia are numerous and aim to measure different constructs, for example, cognition[37] and pain.[38] However, none have been developed to assess the most common distressing symptoms and problems in people with dementia by caregiver staff to facilitate symptom detection and treatment.[10] As dementia is predominantly a disease of older age,[39] it frequently co-exists with other diseases common in old age. As such, people with dementia may experience high levels of comorbidity, resulting in potentially high symptom burden. Our study demonstrates the relevance of palliative care symptoms in this population.[2,40,41] Furthermore, our results indicate the importance and relevance of functional and behavioural concerns when they impact on residents' distress. The inclusion of these concerns in our measure supports comprehensive assessment of symptoms distressing to resident.

Measurement tools used in routine care may result in improved outcomes through systematic assessment and monitoring, changes to care processes, and improved access to treatment.[8] We developed a theoretical model from two existing models[42,43] to understand how using IPOS-Dem in routine care could benefit residents (supplementary file 1). Expected mechanisms of action are improved detection of symptoms and problems, improved integrated working between caregiver staff and health care professionals, shared decision-making and care planning, resulting in changes to care and health care provision and changes to resident or family behaviour. Further evaluation to understand how IPOS-Dem may improve outcomes for residents, and refine the theoretical model, is required.

The limitations of this study need to be considered. As with all studies of this design, there is a risk of researcher bias. To minimise this, analysis was regularly discussed in study supervision to enhance reflexivity. Furthermore, the personal and professional experiences of the researcher were used to enhance the research and analysis, aiding reflexivity. Selection bias through limited access to potential participants is also possible. However, the research team attempted to minimise this by advertising and promoting the research project as widely as possible.

Conclusion

IPOS-Dem is an acceptable caregiver-reported measure for people with dementia in long-term care settings to support comprehensive assessment by unqualified caregiver staff. It incorporates common symptoms and problems experienced by an older population with high levels of comorbidity as well as dementia symptoms. IPOS-Dem has been tailored to maximise caregiver expertise including assessment skills and expert knowledge of residents, taking into consideration caregiver knowledge, remit and training. This study proved essential in refining IPOS-Dem to ensure that it is relevant to the population and setting, and acceptable to caregiver staff, ready for a full psychometric evaluation. Further evaluation is required on how IPOS-Dem can change care to improve outcomes for

residents, its feasibility and how it should be implemented into care processes. IPOS-Dem and resources are available on the POS website: http://pos-pal.org/maix/.

Acknowledgements

The authors would like to thank all staff at the participating centres for support in recruiting and conducting the study and all professionals and family participants for their contribution. The authors thank South London and Maudsley NHS Foundation Trust Older Adults Service User and Carer Advisory Group (SUCAG), Gill Peters, and Caty Pannell for their contribution and study support. BuildCARE is supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy & Rehabilitation, UK. CI: Higginson. Grant leads: Higginson, McCrone, Normand, Lawlor, Meier and Morrison. Project Co-ordinator/PI: Daveson. Study arm PIs: Pantilat, Selman, Normand, Ryan, McQuillan, Morrison and Daveson. We thank all collaborators and advisors including service users. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara A Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J Evans, Taja Ferguson, Lesley Henson, Irene J Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Lara Klass, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Susan Molony, Sean Morrison, Fliss E Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Anastasia Reison, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Rowena Vohora and Gao Wei.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: This study was partly funded by Cicely Saunders International and The Atlantic Philanthropies and partly funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. C.J.E is funded by HEE/NIHR Senior Clinical Lectureship; I.J.H. is an NIHR Senior Investigator Emeritus. This article presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. The funding organisations had no role in the design of the study; collection, analysis and interpretation of the data; or writing of the manuscript.

References

1. Bunn F, Burn AM, Goodman C, et al. Comorbidity and dementia: a scoping review of the literature. *BMC Med* 2014; 12: 192.
2. Mitchell SL, Teno JM, Kiely DK, et al. The clinical course of advanced dementia. *N Engl J Med* 2009; 361: 1529–1538.
3. Lyketsos CG, Lopez O, Jones B, et al. Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment: results from the cardiovascular health study. *JAMA* 2002; 288: 1475–1483.
4. Husebo BS, Ballard C, Sandvik R, et al. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. *BMJ* 2011; 343: d4065.
5. Hendrix CC, Sakauye KM, Karabatsos G, et al. The use of the Minimum Data Set to identify depression in the elderly. *J Am Med Dir Assoc* 2003; 4: 308–312.
6. Watson LC, Zimmerman S, Cohen LW, et al. Practical depression screening in residential care/assisted living: five methods compared with gold standard diagnoses. *Am J Geriatr Psychiatry* 2009; 17: 556–564.
7. Corbett A, Husebo B, Malcangio M, et al. Assessment and treatment of pain in people with dementia. *Nat Rev Neurol* 2012; 8: 264–274.
8. Etkind SN, Daveson BA, Kwok W, et al. Capture, transfer, and feedback of patient-centered outcomes data in palliative care populations: does it make a difference? A systematic review. *J Pain Symptom Manage* 2015; 49: 611–624.
9. Higginson IJ and Carr AJ. Using quality of life measures in the clinical setting. *BMJ* 2001; 322: 1297–1300.
10. Ellis-Smith C, Evans CJ, Bone AE, et al. Measures to assess commonly experienced symptoms for people with dementia in long-term care settings: a systematic review. *BMC Med* 2016; 14: 38.
11. Hearn J and Higginson I. Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. *Qual Health Care* 1999; 8: 219–227.
12. Collins ES, Witt J, Bausewein C, et al. A systematic review of the use of the palliative care outcome scale and the support team assessment schedule in palliative care. *J Pain Symptom Manage* 2015; 50: 842.e19–853.e19.
13. Brandt HE, Deliens L, van der Steen JT, et al. The last days of life of nursing home patients with and without dementia assessed with the Palliative care Outcome Scale. *Palliat Med* 2005; 19: 334–342.
14. Schildmann EK, Groeneveld EI, Denzel J, et al. Discovering the hidden benefits of cognitive interviewing in two languages: the first phase of a validation study of the Integrated Palliative care Outcome Scale. *Palliat Med* 2015; 30: 599–610.
15. Daveson B, Simon S, Benalia H, et al. Are we heading in the same direction? European and African doctors' and nurses' views and experiences regarding outcome measurement in palliative care. *Palliat Med* 2012; 26: 242–249.
16. Ellis-Smith C, Evans C, Higginson I, et al. *Initial development of IPOS-Dem*. London: King's College London, 2014.
17. Care Quality Commission. Care homes, http://www.cqc.org.uk/content/care-homes (2014, accessed 29 January 2014).
18. Goodman C, Baron NL, Machen I, et al. Culture, consent, costs and care homes: enabling older people with dementia to participate in research. *Aging Ment Health* 2011; 15: 475–481.
19. Hussein S and Manthorpe J. The dementia social care workforce in England: secondary analysis of a national workforce dataset. *Aging Ment Health* 2012; 16: 110–118.
20. Morgan DL. *Planning focus groups (The focus group kit)*. Thousand Oaks, CA: SAGE, 1998.

21. Microsoft. Microsoft office, https://www.microsoft.com/en-gb/ (2015, accessed 11 November 2015).
22. Kerr C, Nixon A and Wild D. Assessing and demonstrating data saturation in qualitative inquiry supporting patient-reported outcomes research. *Expert Rev Pharmacoecon Outcomes Res* 2010; 10: 269–281.
23. Murtagh FE, Addington-Hall JM and Higginson IJ. The value of cognitive interviewing techniques in palliative care research. *Palliat Med* 2007; 21: 87–93.
24. Willis GB. *Cognitive interviewing: a tool for improving questionnaire design*. Thousand Oaks, CA: SAGE, 2005.
25. Tourangeau R. Cognitive sciences and survey methods. In: Jabine TB, Straf ML, Tanur JM, et al. (eds) *Cognitive aspects of survey methodology: building a bridge between disciplines: report of the advanced research seminar on cognitive aspects of survey methodology*. Washington, DC: National Academy Press, 1984, pp. 73–101.
26. Hsieh H-F and Shannon S. Three approaches to qualitative content analysis. *Qual Health Res* 2005; 15: 1277–1288.
27. QSR International. *Nvivo 10 for windows*. QSR International Pty Ltd., http://www.qsrinternational.com/products_nvivo.aspx (2014, accessed 1 April 2014).
28. Ahmed N, Bestall JC, Payne SA, et al. The use of cognitive interviewing methodology in the design and testing of a screening tool for supportive and palliative care needs. *Support Care Cancer* 2009; 17: 665–673.
29. Miles MB, Huberman AM and Saldana J. *Qualitative data analysis: a methods sourcebook*. 3rd ed. Thousand Oaks, CA: SAGE, 2014.
30. Sandelowski M. Focus on qualitative methods. The use of quotes in qualitative research. *Res Nurs Health* 1994; 17: 479–482.
31. Tong A, Sainsbury P and Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health C* 2007; 19: 349–357.
32. Payne A, Barry S, Creedon B, et al. Sensitivity and specificity of a two-question screening tool for depression in a specialist palliative care unit. *Palliat Med* 2007; 21: 193–198.
33. Van der Steen JT, Radbruch L, Hertogh CM, et al. White paper defining optimal palliative care in older people with dementia: a Delphi study and recommendations from the European Association for Palliative Care. *Palliat Med* 2014; 28: 197–209.
34. Goodman C, Robb N, Drennan V, et al. Partnership working by default: district nurses and care home staff providing care for older people. *Health Soc Care Community* 2005; 13: 553–562.
35. Goodman C. Care homes and health services: an uneasy alliance. *J Health Serv Res Policy* 2016; 21: 1–3.
36. Palm R, Köhler K, Bartholomeyczik S, et al. Assessing the application of non-pharmacological interventions for people with dementia in German nursing homes: feasibility and content validity of the dementia care questionnaire (DemCare-Q). *BMC Res Notes* 2014; 7: 1–13.
37. Sheehan B. Assessment scales in dementia. *Ther Adv Neurol Disord* 2012; 5: 349–358.
38. Lichtner V, Dowding D, Esterhuizen P, et al. Pain assessment for people with dementia: a systematic review of systematic reviews of pain assessment tools. *BMC Geriatr* 2014; 14: 138.
39. Alzheimer's Disease International. The global voice on dementia, http://www.alz.co.uk/ (2014, accessed 1 November 2015).
40. McCarthy M, Addington-Hall J and Altmann D. The experience of dying with dementia: a retrospective study. *Int J Geriatr Psychiatry* 1997; 12: 404–409.
41. Brandt HE, Deliens L, Ooms ME, et al. Symptoms, signs, problems, and diseases of terminally ill nursing home patients: a nationwide observational study in the Netherlands. *Arch Intern Med* 2005; 165: 314–320.
42. Slade M. Routine outcome assessment in mental health services. *Psychol Med* 2002; 32: 1339–1343.
43. Greenhalgh J, Long AF and Flynn R. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? *Soc Sci Med* 2005; 60: 833–843.

6.2 Summary and next steps

This chapter presents the further development and refinement of IPOS-Dem and its manual by examining its content validity, acceptability and comprehension. In the published paper, the result is called IPOS-Dem final version. This was requested by the editors of the journal. However, to reflect that IPOS-Dem is ongoing development work and that there are likely to be refinements resulting in future versions, this version is called Version 3 in the thesis. IPOS-Dem Version 3 and its manual is presented in Appendix P, ready for the evaluation in routine care of people with dementia in residential care homes.

7. Development/pre-implementation qualitative and evaluation/post-implementation mixed methods phases: feasibility and process evaluation of IPOS-Dem [PUBLICATION 3]

This chapter presents a manuscript which has been submitted to PLOS One and is currently under review (publication 3). The chapter presents results from a feasibility and process of evaluation of IPOS-Dem utilising results from the development/pre-implementation and evaluation/post-implementation phases, addressing the study objectives four, five, six, and seven. Presented again here for convenience:

IPOS-Dem development/pre-implementation objectives:

4. To gain an understanding of the residential care home context, the likely mechanisms of action, implementation requirements, and acceptability and feasibility of IPOS-Dem in the development phase to inform its use in routine care in preparation for evaluation phase.

IPOS-Dem evaluation/post-implementation objectives:

5. To understand the mechanisms of action and potential benefit of IPOS-Dem used in routine care of people with dementia within the residential care home context.
6. To gain an understanding of the implementation requirements of IPOS-Dem into routine care of people with dementia.
7. To test the acceptability and feasibility of IPOS-Dem in routine care of people with dementia.

How can a measure improve assessment and management of symptoms and concerns for people with dementia in care homes? A mixed-methods feasibility and process evaluation of IPOS-Dem

Clare Ellis-Smith[1*], Irene J Higginson[1,2], Barbara A Daveson[1], Lesley A Henson[1], Catherine J Evans[1,3], On behalf of BuildCARE[^]

Author Affiliations:

[1] Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, King's College London, London, UK

[2] King's College Hospital NHS Foundation Trust, London, UK

[3] Sussex Community NHS Foundation Trust, Brighton, Sussex, UK

* Corresponding author

E-mail: alexandra.c.ellis-smith@kcl.ac.uk (CES)

[^] Membership of BuildCARE is provided in the Acknowledgements

Abstract

Background: Assessment of people with dementia is challenging; with undetected and under treated symptoms and concerns resulting in avoidable distress, and few evidence-based interventions to support this. We aimed to understand the mechanisms of action of a measure to support comprehensive assessment of people with dementia in care homes; and its acceptability, feasibility, and implementation requirements.

Methods: A mixed methods study in three residential care homes, underpinned by a theoretical model of mechanisms of action. The measure, the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem), was introduced into the care of residents with dementia for 12 weeks. Qualitative data comprised focus groups and semi-structured interviews with family members, care home staff, general practitioners and district nurses; and non-participant observations. Quantitative data comprised IPOS-Dem data. Directed content analysis for qualitative data, and descriptive statistics were used for quantitative data.

Findings: Key mechanisms of action were: improved observation and awareness of residents, collaborative assessment, comprehensive 'picture of the person', systematic record keeping, improved review and monitoring, care planning and changes to care provision, and facilitated multi-agency communication. Potential benefit included improved symptom management, improved comprehensive care, and increased family empowerment and engagement. IPOS-Dem was found to be acceptable and feasible. It was perceived as quick and easy to use, with proportion of overall missing data decreasing from 2.1% to 1.1% from baseline to final time points. 'Trust' in the measure was important; and leadership essential to ensure integration into care processes.

Conclusions: In a population with complex care needs, with challenges to assessment and barriers to multi-agency working, a measure introduced into routine care is feasible and acceptable, and supports assessment and management of symptoms and concerns. A theoretical model demonstrating the likely mechanisms of action was developed. Further evaluation is required to test its effectiveness.

Introduction

Dementia is a progressive and terminal illness [1]. It is characterised by increasing dependence and disability [2, 3] meaning that 24-hour care is frequently required [4]. Worldwide demographic change of increasingly older population profiles will result in growing prevalence of dementia [5, 6]; with consequent increasing demand in care home provision, and increasing requirement for palliative care from non-specialist providers [6], including care home staff.

People with dementia may experience high symptom burden [7, 8] due to dementia, multi-morbidities [9] and side-effects of treatments. It is challenging to assess symptoms and concerns in people who may have difficulty verbally expressing their wishes and concerns. This impedes practitioners' ability to assess symptoms and concerns and often leads to under detection and treatment; and increased distress, behavioural changes and reduced quality of life [10]. Practice guidelines recommend comprehensive assessment and non-pharmacological interventions to identify and treat the underlying causes of behavioural changes such as agitation [11]. However there are few high-quality evidence-based interventions for care homes to improve comprehensive assessment and management of symptoms and concerns in this population [12-15]. Furthermore, in the UK particularly, there are barriers to accessing health care for residents in care homes that have no onsite nursing care and therefore rely on external providers, including General Practitioners (GPs) and community or district nurses (DNs), with inconsistencies in provision across the country and challenges to integrated working [16].

Measures used in routine clinical care can facilitate assessment and change care processes leading to improved patient outcomes [17]. However, little is known of their use in care home settings [17]. Measures used in this way are complex interventions [18, 19]. In developing and evaluating complex interventions it is important to understand the likely mechanisms of action, and potential harms and safety of the intervention [19, 20], how the intervention should be implemented, and any influencing contextual factors [21, 22]. This

is particularly the case in the residential care home sector where there are additional challenges of multi-agency, integrated working (including with family) [16, 17].

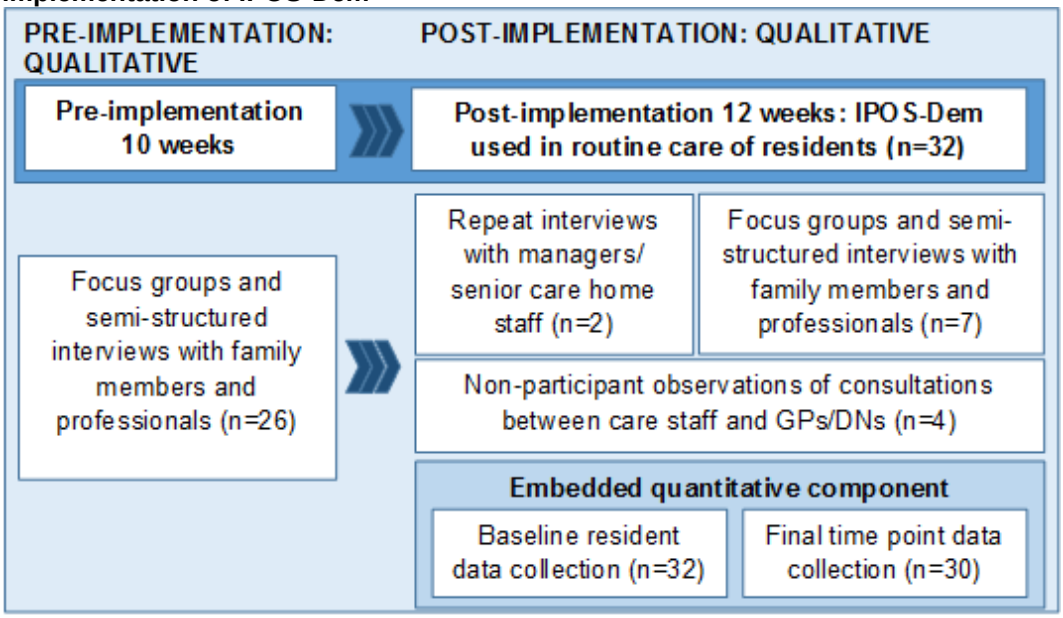
We aimed to explore the mechanisms of action, feasibility, acceptability and implementation requirements of a measure, the Integrated Palliative care Outcome Scale for Dementia (IPOS-Dem), used in routine care to support comprehensive assessment of symptoms and concerns of care home residents with dementia and their family members.

Methods

Study design

We conducted a two phase pre-implementation and post-implementation qualitative study with a concurrent embedded quantitative component [24] (Fig 1), underpinned by a theoretical model of the likely mechanisms of action of a measure used in routine care for people with dementia in residential care homes [25-27].

Fig 1: Study design and research methods of pre-implementation and post-implementation of IPOS-Dem



IPOS-Dem was implemented into routine care of residents with dementia for 12 weeks. Qualitative data collection included pre-implementation focus groups and semi-structured

interviews with family members (including friends) and professionals (care home staff, GPs, DNs); and post-implementation (during and towards the end of implementation) focus groups and semi-structured interviews with family members and professionals, and non-participant observations. Quantitative data collection comprised measures with residents at baseline and at 12 weeks. Throughout the planning, data collection and analysis of the study, we consulted with experts including service users and carers, and academics and health care professionals in palliative care, primary care and mental health.

Setting

Three residential care homes registered to provide care for people aged 65 and over in a London borough, United Kingdom. Unlike nursing homes, residential care settings are not required to employ professionally qualified nurses, and therefore have no onsite nursing. The main health care providers are GPs and DNs [28]. Settings were recruited to obtain a variety of funding types, ownership and dementia-registration [29].

Participant recruitment

Recruitment of residents was informed by the Mental Capacity Act [30]. Eligible residents were identified by senior staff in the care homes. The care home staff introduced residents to the research team. The research team met with residents to ascertain willingness to participate and assess mental capacity to consent for themselves. Those residents that had capacity gave written informed consent. As we anticipated that the majority of residents would only be able to consent in the moment, we took the approach of gaining the advice of consultees in addition to informed consent [31]. The care home therefore sent a letter on behalf of the research team to a close friend or family member to invite them to advise on whether the resident should participate in research (personal consultee). Two letters were sent. If no response was received after one week of the second letter being sent, a nominated consultee was asked to advise on resident participation [30]. The nominated consultee was independent from the research study and used all available information

(including meeting with the resident, reviewing case notes and speaking to care home staff) in order to give advice on resident participation.

At each recruitment phase we advertised and held coffee mornings in the care homes to share study information with family (including friends) of residents with dementia (CES/CP) [32]. Interested family members shared their contact details with the research team. Post-implementation, we contacted family members acting as personal consultees in the recruitment of residents lacking capacity [30] who had expressed interest in participating and shared their contact details. We made up to two attempts to contact family members to recruit them. Recruitment of care home staff for both phases involved formal and informal meetings with managers and care home staff. GPs and DNs responsible for health care provision for the participating care settings were identified and invited to participate. All participants were provided with study information sheets at least 24 hours prior to participating, and gave written informed consent (CES/CP/LAH).

Participant eligibility criteria

Participants for the focus groups and semi-structured interviews comprised family members and professionals. Non-participant observations of meetings were conducted between GPs and/or DNs, and senior care home staff to discuss and review residents' care. Managers or senior care home staff participated in repeat semi-structured interviews about feasibility and implementation requirements of using the measure.

All care home staff working at the participating settings were eligible to participate. Eligibility criteria for family were 18 years or older, able to provide consent and English-speaking. Additionally, post-implementation, family members were relatives or friends of residents recruited to receive IPOS-Dem intervention. Care home staff were purposively sampled to provide a range of seniority and care roles. GPs and DNs were eligible to participate if they were responsible for providing health care to the participating settings. All family and health care professionals (GPs and DNs) meeting the inclusion criteria were invited to participate.

Eligibility criteria of residents were a permanent resident of the care home, formal diagnosis of dementia or cognitive impairment of stages four to seven on Functional Assessment Staging (FAST) [2].

IPOS-Dem intervention

IPOS-Dem [27] formed the intervention. IPOS-Dem is developed from the Integrated Palliative care Outcome Scale [33]. IPOS-Dem was developed to support assessment of symptoms and concerns in care home residents with dementia by care home staff without a nursing qualification (unqualified care home staff) [27]. IPOS-Dem comprises twelve questions covering common symptoms and concerns experienced by people with dementia over the past week. Each item is rated on a five-point scale from 0 (no problem) to 4 (very severe). The first question is unscored and is a free text response option of the main problems experienced by the resident. IPOS-Dem can be accessed and downloaded for free [34].

An early version of IPOS-Dem [27] was examined pre-implementation to understand likely mechanisms of action, and understand how IPOS-Dem should be implemented into routine care, and an instruction manual developed based on the results [27, 35].

During implementation, participating care homes were given a refined version of IPOS-Dem and asked to use it, according to the instruction manual with recruited residents. The instruction manual recommends that IPOS-Dem is used monthly at the time of care plans, or flexibly at times of resident change. Apart from at the baseline and final time points, the research team was not involved and did not prompt care home staffs' use of IPOS-Dem through the course of the implementation phase. This was to understand the implementation of IPOS-Dem without the use of facilitation [36] which is frequently not available or sustainable in under-resourced care settings [37].

Demographic and clinical data collection

Family and professional demographic data:

Demographic data on family and professional participants were collected using standardised data collection forms, collected by the research team from participants. Demographic data for family included relationship to resident, gender and age. Professional demographic data were profession or role, years of experience, gender, and ethnicity.

Resident demographic and clinical data:

We used a data collection form and extracted demographic and clinical data from case notes at baseline. Demographic and clinical data included resident age, diagnosis of dementia (yes/no), type of dementia, gender, ethnicity, FAST dementia staging (from case notes and care home staff), morbidities and medication.

Qualitative data collection

Pre and post-implementation focus groups and semi-structured interviews:

Separate focus groups were conducted with family members and professionals. Focus groups were chosen as a method of data collection to obtain participant interaction data [38]. Semi-structured interviews were conducted to enhance data richness by alternative data collection methods [39]. The pre-implementation topic guide consisted of a PowerPoint [40] presentation on the purpose of IPOS-Dem. To stimulate discussion about how IPOS-Dem could benefit residents and family members, and requirements for its properties and implementation, we used case vignettes within the topic guides (S1 file) [41]. Post-implementation topic guides was informed by the findings of the previous phase and also included questions on IPOS-Dem mechanisms of action, measurement properties and implementation requirements. Topic guides for the manager interviews were similar, but included additional questions on implementation requirements and feasibility within the care home setting and the resources available. All topic guides were reviewed by expert members, and piloted and refined before being used in the main study. Given the potentially

sensitive nature of the focus groups and interviews, a distress protocol was developed. Focus groups and interviews were digitally recorded. All focus groups and the majority of semi-structured interviews were conducted in the care homes. One interview with a family member was conducted in her own home in accordance with her preference.

Non-participant observations:

Non-participant observations were conducted in the care homes of care home staff and health care professionals discussing and reviewing residents to further understand the process of integrated professional working, and a means of data triangulation. Observations of consultations between senior care home staff and visiting health care professionals occurred at regular intervals through the intervention period and field notes made.

All qualitative data collection was conducted by CES (female; BSc, MSc), an Occupational Therapist with clinical experience in older adult mental health and dementia, who at the time of the study was a PhD Training Fellow. A second researcher (CP/LAH) was present for focus groups to record observations and implement the distress protocol if required. Data collection continued until data saturation was achieved. This was defined as the point where no new themes or subthemes were being generated from further data collection [42, 43].

Quantitative data collection

Data collection time points (Fig 1):

Resident baseline data collection occurred just prior to implementation of IPOS-Dem in routine care. Final time point data collection occurred at 12 weeks at the end of implementation of IPOS-Dem. Baseline data collection consisted of a measure of agitation, the Cohen-Mansfield Agitation Inventory (CMAI) [44] and a measure of function, the Barthel Index [45]. At both time points, IPOS-Dem with an attached utility questionnaire, were completed.

IPOS-Dem utility questionnaire:

For the purposes of the study, a brief utility questionnaire was included at the end of each IPOS-Dem to be completed by care home staff using the measure. This comprised four brief questions regarding the acceptability and usefulness of IPOS-Dem (S2 file).

Qualitative data analysis

All recordings were transcribed verbatim and detailed field notes were made, and entered into Nvivo 10 [46] to aid data management and analysis. Transcripts were checked against the original recordings by CES to ensure accuracy. Data were analysed using directed content analysis [47]. A coding framework was developed informed by the theoretical model [27]. Additional codes were developed during analysis for relevant data that could not be coded into the existing framework [47]. One researcher conducted all coding (CES). A second researcher (CJE) coded a selection of interviews independently. Where coding differed, this was discussed and reviewed until consensus was reached and the coding framework was revised based on consensus. The full set of transcripts were then recoded using the finalised coding framework (CES). The codes were then inductively categorised into themes and subthemes. To triangulate the data, family and professional data, and pre-implementation and post-implementation data were compared and contrasted [48]. All analysis was discussed in regular research supervision (CJE, BAD, IJH) to enhance reflexivity and ensure accurate representation of findings.

Quantitative data analysis

Quantitative data were analysed using simple descriptive statistics for demographic, clinical, IPOS-Dem and IPOS-Dem utility questionnaire data. To explore for patterns of missing baseline IPOS-Dem data [49] (all missing, 'missing - cannot assess', 'missing – reason unknown') across cases, we used X^2 or Fisher's exact test with a Bonferroni-corrected alpha level of $p<0.003$. Assumptions (normality, outliers) were tested prior to all analysis. Pearson's r and paired t-test (for parametric) or Spearman's rho and Wilcoxon signed ranked test (for non-parametric data) were used to examine correlation and mean

difference between baseline and final time points scores respectively with Bonferroni-corrected alpha level of $p<0.004$. Analyses were conducted both without imputation and using two methods of imputation (mean item score and mean case score) [49]. All analyses were conducted using SPSS version 22 [50].

Ethics

Ethical approval was obtained from the National Research Ethics Committee – London South East, a committee flagged for adults lacking capacity [NRES: 13/LO/1339], and Local Authority Research Governance Framework approval was obtained for research in social care settings. Where required, individual care home setting ethical approval was obtained. National Health Service (NHS) research governance approval was obtained for participating NHS staff from the respective NHS employers.

Findings

Settings

Recruited care home size ranged from 26-33 beds. No relationship existed between the research team and care homes prior to the study commencing. Pre-implementation data collection commenced in May 2014 and completed in July 2014. Resident recruitment commenced in July 2015 and finished in October 2015. Baseline data collection commenced in September 2015 and the study closed with final time point data collection in February 2016.

Prior to implementation, one of the study sites had a change of management and high staff turnover, resulting in withdrawal from the study. As a result, only two settings participated in the post-implementation phase.

Participants

Pre-implementation, we conducted qualitative focus groups (n=4) and interviews (n=3) with six family members and 20 professionals comprising care home staff (n=15), GPs (n=3) and DNs (n=2) (S1 Table). Four family members who expressed interest and shared their contact details did not participate due to time commitments (n=1), non-contactable (n=1), did not arrive (n=2). All care home staff who were approached and available participated. Four GPs were approached, one declined citing workload reasons. Three DNs were approached and expressed interest but one was unavailable due to work commitments.

During the IPOS-Dem implementation period, we conducted three non-participant observations with three senior care home staff and one GP in one care home. Also during the IPOS-Dem implementation phase we conducted two sequential interviews with both care home managers. Towards the end of the IPOS-Dem implementation period, we conducted focus groups (n=2) and qualitative interviews (n=7) with seven family members and five care home staff. For family members, thirteen expressed interest and shared their details to be contacted and were therefore sent details of the study. Eleven responded after two contact attempts. One declined due to his relative's deteriorating health. Of the ten remaining family members, six and an additional family member of one participant took part. Four expressed interest but were unavailable to attend. Care home staff working and available at the time of the focus group participated in the focus group (n=4). One care home staff member was recruited to participate in a semi-structured interview. One GP was approached to participate in focus groups but could not be recruited due to time constraints [S1 Table].

The mean length of focus groups was 77 minutes (range: 62-92), total 7 hours and 41 minutes. The mean length of interviews was 49 minutes (range: 26-91), total 8 hours and 5 minutes. In the post-implementation phase, none of the family members had awareness of IPOS-Dem being used with their relatives. All participating care home staff had used IPOS-Dem in the study, apart from the managers who had awareness of the care home staff's use of IPOS-Dem.

Baseline and final time point data were collected for 32 residents and 30 residents respectively. One resident died and another moved to a nursing home due to complex care needs. S1 Fig. shows flow diagram of recruitment, including consenting process, and reasons for attrition. Table 1 includes demographic and clinical data of participating residents. Care home staff completed utility questionnaires were returned for all 32 baseline resident assessments and all 30 resident assessments and final time point.

Table 1: Baseline demographic and clinical characteristics of participating residents

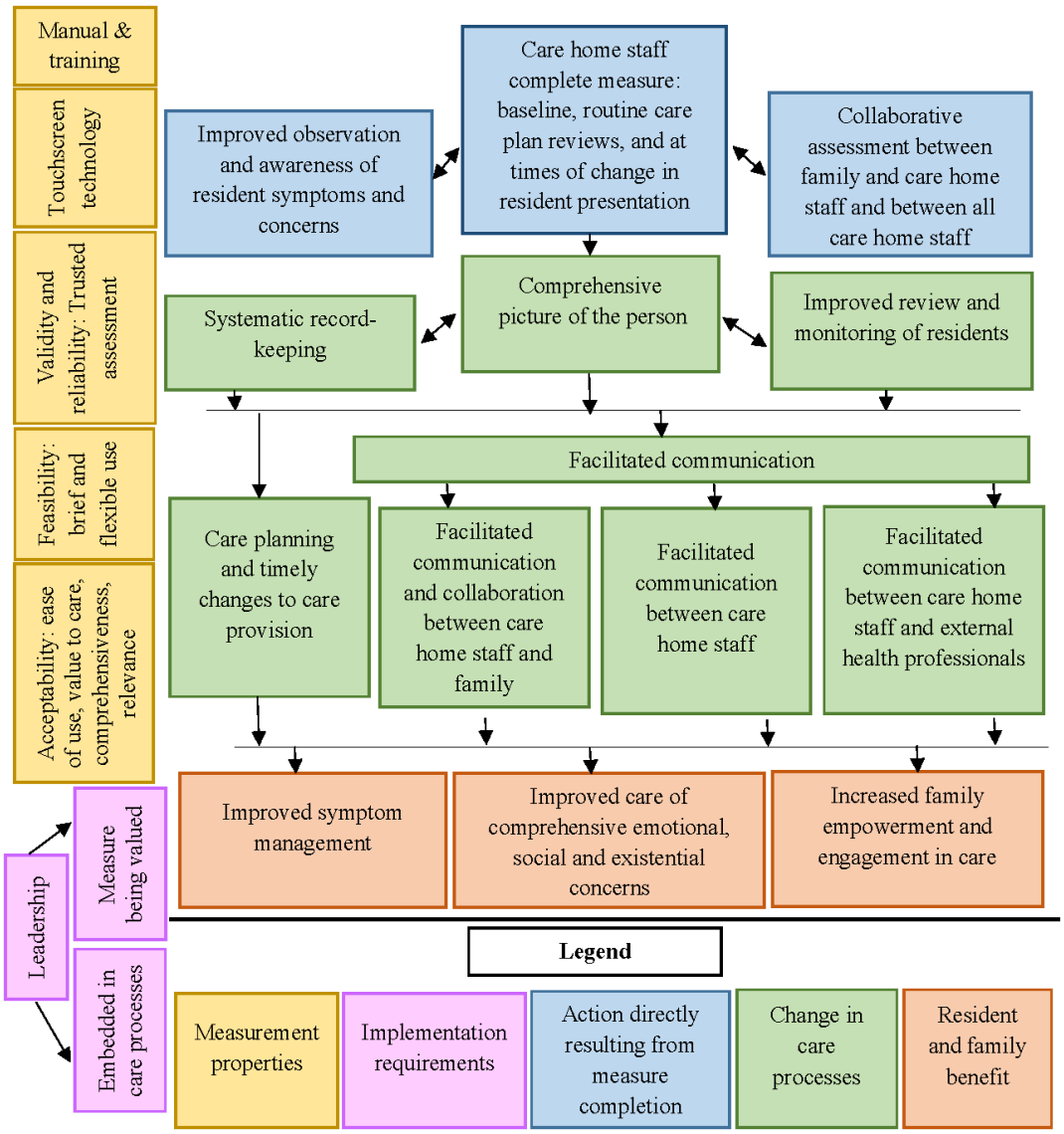
Variable	Residents n=32 (%)
Socio-demographic details	
Age	
Mean (SD)	87.2 (8.3)
Median (range)	89 (67-102)
Sex	
Male	8 (25)
Female	24 (75)
Ethnicity	
White British, Irish or other	28 (88)
Black Caribbean	4 (13)
Clinical details	
Formal diagnosis of dementia	
Yes	25 (78)
No	7 (22)
Dementia subtype	
Alzheimer's disease	4 (13)
Vascular dementia	6 (19)
Alzheimer's disease – mixed type	7 (22)
Unspecified dementia	1 (3)
Missing	9 (28)
Not applicable	7 (22)
Functional Assessment Staging dementia stage	
4-5: Mild dementia to moderate dementia	4 (13)
6a- 6e: Moderately severe dementia	24 (75)
7a-7f: Severe dementia	3 (9)
Agitation	
Mean (SD, range) Cohen-Mansfield Agitation Inventory (29-203)	50.3 (14.0, 29-93)
Functional status	
Mean (SD, range) Barthel Index (scores 0-100)†	52.7 (24.7, 0-90)
Morbidities (excluding dementia) [9]: Resident number of morbidities	
Mean (SD)	5.1 (2.1)
Morbidities (excluding dementia) [9]: Morbidity by group	
Cardiovascular	51
Musculoskeletal	21
Sensory diagnoses or impairments	18
Psychiatric	15
Diabetes	10
Cancer	8
All other	40
Medication: Resident number of medications $	
Mean (SD)	6.3 (2.6)
Missing	5
Medication types across all cases	
Cardiovascular	65
Analgesia	10
Laxatives	18
Antidepressant/ mood stabiliser	9
Antipsychotic	4
Dementia medication	6
Other	58

SD: standard deviation
† Higher scores indicate greater independence
¶ Higher scores indicate increased agitation
$ Medication missing for 5 residents

Key findings

Key findings from all the data are summarised here, and explored in more detail in the subsections that follow. Challenges to symptom identification and communication were identified. Key mechanisms of action of using IPOS-Dem were: (1) improved observation and awareness; (2) collaborative assessment; (3) comprehensive 'picture of the person'; (4) systematic record-keeping; (5) improved monitoring and review; (6) care planning and changes to care provision; and (7) facilitated communication. Potential resident and family benefit were identified as: (1) improved symptom management; (2) comprehensive concerns being addressed; and (3) increased family empowerment and engagement in care. Measurement properties included: (1) acceptability of IPOS-Dem: easy to use with low missing scores and providing value to care, and relevant and comprehensive; (2) feasibility: perceived to be quick to complete, with flexible frequency. Important measurement properties were identified as: (1) 'trusted' as an assessment i.e. known validity and reliability and established as a recognised measure; (2) administered using touch-screen technology. Leadership was essential to ensure that the measure is integrated in care home processes, and that it is valued and recognised as a tool to improve care processes and outcomes. These findings are combined in Fig 2 to illustrate the theoretical model of mechanisms of action, measurement properties, and implementation requirements. S2 Table includes model components with underpinning participant narratives.

Fig 2: Theoretical model of a measure used in routine care of people with dementia in residential care homes



Mechanisms of action

Improved observation and awareness of resident symptoms and concerns

In both phases, all participants reported that IPOS-Dem supported improved awareness of residents' symptoms and concerns. Family participants expressed concern that IPOS-Dem may be less useful for experienced care home staff, and therefore less value for the time spent completing it, but would be a good training tool for new care home staff:

'and I think this is a really good learning tool, this is what we're looking for, this is the sort of thing that will affect people erm and some people will already know this, they will have sort of walked in maybe having already had erm, erm experience with dementia and they will know this; but most people need it breaking down and so I think the fact that it's broken down into this level of detail must be really useful when you're starting to work in the care environment but I, I imagine that some of the people who are, who have worked there for many years probably could recount this in their sleep, erm and to actually have to constantly reiterate it would be diffi – more difficult … it's still time when you could be interacting with residents' (Family A3004)

Care home staff identified that it prompted them to think more about resident symptoms and concerns:

'We understood the questions but I think you have to think deeply about what may be the answer you might think of. As a resident, as an individual maybe you don't quite think quite so deeply until someone asks you that question' (Care home staff B3011)

Collaborative assessment between family members and care home staff and between all care home staff

Care home staff identified that sometimes they had gaps in their knowledge of residents, particularly regarding to residents' earlier lives. Findings from both family and professional participants suggested that using IPOS-Dem could address this through facilitating consultation with family members in the assessment of residents:

'Isn't this where we come in? As much as we can obviously give some history as to how our parents or whoever it is, um what their personality was, you know, and so we can contribute and say that prior to the diagnosis of dementia they were a difficult person anyway' (Family B1009)

Furthermore, completing IPOS-Dem prompted care home staff to discuss residents amongst themselves further improving assessment and awareness of resident concerns:

'Particularly if someone's sitting near to somebody else when they're completing it and they might just say 'what do you think about this?' so it's actually prompting

conversation which maybe in some senses you're saying the document is meant to be really clear but as a care manager, I think it's brilliant that anything that prompts conversation between staff about a resident' (Manager B3001.1)

Comprehensive 'picture of the person'

Pre-implementation, family and professional participants expressed concerns that IPOS-Dem would not provide sufficiently detailed assessment, and that a much more comprehensive and thorough assessment could be obtained through written text in care plans. As a result, participants reported that time would be wasted by care home staff completing IPOS-Dem without the provision of any meaningful information. Conversely, post-implementation, IPOS-Dem was seen as comprehensive and enhancing the assessment process. Participants valued how IPOS-Dem provided a comprehensive overall 'picture of the person':

'Erm it sort of put you in the mind of, although we're doing care plans and we're doing report but it gives you a picture as well you know that you, you're seeing a picture of a person when you're doing this so yeah it do helps (Care home staff A3003)

This provided benefit by allowing a comprehensive knowledge of any concerns about a resident from a brief look at IPOS-Dem. Participants reported this as much more favourable compared to going through lengthy case notes.

Systematic record-keeping

Participants in the post-implementation phase reported that IPOS-Dem would result in improved record-keeping. Completing IPOS-Dem and severity scoring, was reported as an efficient means of recording residents' symptoms and concerns over time, and easier to access compared to existing case notes:

'Okay so say for instance, let's go with the skin broken down. For weeks now Mrs So and So's skin broken down, you've got a variance, you've got it's changed, "not at all" to "moderately". The moment you have something that maybe goes over 2 boxes, page so and so this is what we did … almost like yeah so you're evidencing you've seen the change and you've actioned something' (Manager B3001.2).

Improved review and monitoring of residents

Participants in both phases identified the potential benefit of IPOS-Dem in monitoring residents over time. IPOS-Dem used regularly could facilitate early detection of symptoms and problems, 'refresh the brain' by enabling care home staff to review how residents have been over time, provide information on patterns of behaviour, and inform end-of-life care through knowledge of residents over time:

'or that would help them towards the end of life though because all that information you've got about that person could be used … yeah because if they suffer from depression or they're particularly low or there's different things you know about that person when it comes to the end of life you'd have more of an understanding about whether they're in pain or… (Care home staff B3011).

Care planning and timely changes to care provision

Participants reported that IPOS-Dem could be used to inform care plans, and result in changes to care provision:

'And indeed [care home staff] using it to be an additional either reinforcement or even a step beyond, um and then to get into especially towards the end of life, and it does mean anticipating, it does mean early identification and action…' (GP B1004)

Participants also shared how IPOS-Dem could also result in improved access to health care through improved identification of symptoms and improved communication. A few participants identified the potential benefit of having an IPOS-Dem action plan, ensuring that any identified concerns trigger a change in care:

'that's right so some way of dragging together the bits that are more worrying than other bits, putting them together into a co – what do you call them and email in sort of data terms but you know putting the data together and creating an answer which says, you know there's a red light on this, you know giving red, orange and green lights really you know that patient or that care, or that care patient has got red lights we've got to keep an eye on him or her, she's green she's fine, she's okay at the moment, that's really the …' (Family B3008)

However, some participants identified that there may be a risk of identifying problems but not acting upon them:

'You know if we are because we're in the situation where we're thinking everybody's exactly the same and then suddenly the data comes back saying actually you aren't identifying that there have been quite significant changes which are written down but nobody's doing anything about. Because the problem with care plans is you write things down but you don't necessarily act on them' (Manager B3001.1)

Facilitated communication between family members and care home staff

All participants identified challenges of communication between family members and care home staff. Many family members identified problems with communication with care home staff, with challenges in accessing information in a timely manner. This was exacerbated by shift work. Information, when provided, was rushed and not adequately discussed:

'… I'm sure there is a record on my mum but even when I, you know I meet with them they don't get it out and look at it you know, erm and I have said before now I'd like to come in and talk to you about her but they just say oh she's taking all her tablets and …' (Family A3002)

Care home staff identified challenges in communicating with family members. Barriers to communication were lack of confidence, concerns about causing distress to family, concerns about not giving accurate information, or not knowing the answers to family questions:

'One has to be very um polite see, in a case like that it's crucial and one has to be very aware of the kind of information (Care home staff B3012)…information you give (Care home staff B3014) … how you give it and what you're going to say, some are sensitive so it's a very difficult (Care home staff B3012)…especially if someone's at the end of life' (Care home staff B3011) (Care home staff focus group)

A tension was identified regarding whose role it is to communicate. Family members tended to prefer communication with managers. Care home staff referred family members to managers for any more complex information, while one manager in particular, considered

it important that care home staff are enabled and skilled to communicate with family members:

'One of the things that really frustrates me is when staff say well speak to the manager – no you're looking after the person, you tell them, and with this tool [IPOS-Dem] you can' (Manager B3001.2)

Family participants welcomed the potential opportunity of accessing information and overwhelmingly reported the wish for IPOS-Dem assessments to be shared with them, and the potential benefit to care as a result:

'If the staff were completing this on a weekly basis, can I come down and say, can I see what [they've] said about my mum? (Family A1006) … So would that be useful? (CES) …Oh God, yes (Family A1006) …Yeah (Family A1007)' (Family focus group)

While the majority of care home staff perceived IPOS-Dem as a means of easily conveying information to family members:

'but maybe with this [IPOS-Dem] they don't have to go because some of them can't be bothered to sit there all, going through the care plan, where this you could just say okay we're using this now, as well as a care plan, if you don't have time to go through, look through this and you can see why we're saying that your dad or your mum needed more support you know so then they can look through and see what we're going on about (Care home staff A3003)

Post-implementation, participants discussed the possibility of family members disagreeing with care home staff assessment, and the potential negative impact of this. This was contrasted with perceived potential benefit as a result of improved dialogue:

'but you can always look through and you could always say to them if you not agree with what we've said in here then, with all means you could see a different picture from what we see because we are looking here looking after mum or dad, you could come in and see something else that we've missed so yeah you know so we could always say if you think that something I should add in then let us know and we could improve from that as well' (Care home staff A3003)

However, for this to occur, the importance of a culture of transparency and lack of defensiveness was highlighted by both family and care home staff participants:

'I think you know I think anyone who's looking after your parents have to be, have to be engaged, very engaged with you and have to be very honest with you and you have to be very honest with them really' (Family A3004).

Participants, particularly care home staff, expressed concern that sharing IPOS-Dem with family members may result in distress if the information was sensitive or unexpected. However, there was also recognition of the importance of transparent communication with family members. Family participants overwhelmingly identified the benefit of being able to access IPOS-Dem assessments, and did not identify any concerns about potential distress of seeing assessments.

Facilitated communication between care home staff

Participants post-implementation identified how IPOS-Dem could support communication between care home staff. IPOS-Dem was considered potentially useful for care home staff returning to work after time off as a means of quickly getting an update on resident changes or concerns:

'… and certainly one of the things I've considered is if somebody's been on annual leave saying to them make sure you read the [IPOS-Dem]. I haven't done it yet, but almost like on your first day back, the first thing you've got to, the thing you've got to achieve before the end of your first day is read – is just checking on every resident and you can't do that with the normal care plans but I think you could do it with this' (Manager B3001.2)

Also post-implementation, participants identified the usefulness of IPOS-Dem in supporting communication between junior and senior care home staff:

'I've had more staff come to me regarding 2 residents having difficulty swallowing in the last 2 months than I think I've had in the last 2 years all of a sudden erm I don't think she's swallowing properly, I think she's holding it in her mouth…' (Manager B3001.1)

Senior care home staff valued the potential ability to return from leave and quickly and easily get a resident update through looking at IPOS-Dem assessments. Senior care home staff and managers also identified how IPOS-Dem could support supervision. Participants suggested that IPOS-Dem could help them monitor the quality of junior care home staff

assessment, and ensure that care home staff are acting upon any symptoms or problems identified:

'supervising [junior care home staff] to see that they are actually knowing the clients that they're looking after' (Care home staff A3003)

One manager, however, expressed concern over the potential additional burden of supervising whether care home staff had accurately assessed residents and acted upon identified concerns.

Facilitated communication between care home staff and external health care professionals

All participants in both phases shared communication challenges between care home staff and external health care professionals. Barriers to communication were shift work, high health care professional turnover, time limitations, differing expectations, and lack of shared documentation.

Participants in both phases identified how IPOS-Dem had potential to support communication with health and social care professionals. This was particularly the case in working with mental health professionals. However, as was evidenced by observations of GP consultations and expressed by participants in both phases, there was uncertainty as to whether GPs would have time to read documents:

'The real issue is whether I suppose in a way maybe the other thing to think about is whether there should be some trigger so that the care workers refer forms which they think the GP should see, to the GP so that they do the sifting because the GP won't do it for sure, I mean you give him a pile of forms like this he'll say forget it. Um but if the carers say well there's 2 forms here that we think you should look at because this lady's had diarrhoea and then you know been vomiting and that kind of stuff' (Family B3008)

Potential benefit to residents and family members

Improved symptom management

Participants reported that symptoms identified through IPOS-Dem prompted treatment:

'Yeah I mean I can certainly think of one resident who erm has recently started to suffer with constipation and that was highlighted in this and now they're on a laxative which you know so I know this was used for that so – ' (Manager B3001.2)

Improved care of comprehensive emotional, social and care concerns

In both study phases, care home staff participants identified the usefulness of a comprehensive measure to detect resident concerns, and improve the care provided to residents:

'Because if you're finding things out from this and you're making the lives of clients better, whether it be in a health way, or whether it be mentally, physically, in whatever way, then that's a good thing, something you might not have picked up on without this' (Manager C1005)

Increased family empowerment and engagement in care

In the post-implementation phase some but not all participants identified how IPOS-Dem could help increase family member empowerment to advocate for the resident and help to engage in their care:

'Erm yeah I do because if maybe she had diarrhoea for - then I could possibly pick up on it you know and say to them have you done anything about this?' (Family A3002)

The same family member, however, reported that even using the measure would not help her overcome the challenges of communication:

'[sighs] I think some family members could, yes, I do I think as a whole family members could question it, it might make them think a bit more and I could just imagine I wouldn't, I might not say anything because I'm that sort of person, I think I give up so, and

I shouldn't, someone said something was done in the hospital recently, when I went to the hospital this week and someone said well didn't you say and I thought what's the point, if they're in that profession and they don't see that, you know my mum was supposed to be keeping this thing on her eye and she kept moving it and she went "put it back", and you think don't talk to her like that, but I thought, if, if I have to tell you then you're not going to change you know what's the point in having an argument you know with someone and I think maybe I don't speak up when I should at times, you know and I think if this, if they ticked that they'd communicated with me, I think there's a chance I might not say anything (Family A3002)

Measurement properties

Acceptability: 'ease of use' and 'value to care'

Care home staff overwhelmingly reported that IPOS-Dem is easy to use and understand. IPOS-Dem was reported to provide value to care. The value was enhanced by care home staff understanding the purpose IPOS-Dem and valuing how it can help and contribute to improving and supporting care provision. Care home staff participants reported that all care home staff should use IPOS-Dem with residents and that it is sufficiently accessible for all care home staff providing care no matter what their seniority is:

'I should think so because I mean we're all doing the same job, we all write care plans …' (Care home staff B3013)

Only one participant, a manager, expressed concerns about all care home staff using IPOS-Dem, due to time constraints and literacy skills:

'I think mostly it's time because they are so involved in the practical needs of the residents you know, um plus a lot of them don't have very good you know handwriting [literacy] skills and that kind of thing, they weren't employed for their handwriting skills' (Manager A3001.1)

Care home staff participants discussed the challenges of assessing residents who have difficulties expressing their wishes and concerns, and that there is always a degree of uncertainty in the assessment of these residents:

'I think sometimes when you're talking about pain or you're talking about the way that person might be feeling you have an idea of the way they might feel but you don't really know how they are feeling because they can't express themselves so …' (Care home staff B3011)

However, they spoke about the benefits of knowing residents well to inform assessment, and the requirement to closely observe behaviour to inform assessment:

'We are looking after the resident you see some who cannot express themselves but as a carer you notice that oh this resident, where he would try to um to behave you can see the face, the way he would do um the way he would make the face you know that oh this resident he have pain somewhere or he will hold, sometimes he will hold his stomach like that then you know oh maybe she got a pain in her stomach, maybe she constipated or maybe, so things like that they will make the sign that you, you feel that maybe she have pain' (Care home staff B3014)

A few items were considered potentially problematic. The usefulness and challenge of the item, 'family information' was discussed by participants. Family participants expressed the importance of this item, but concern that care home staff would not be able to accurately respond to this:

'They're making a guess, that everybody in the family has had enough information as they want whether they've verbalised it or not; so they can only say have the family asked for more information and has it been provided, not that they want more' (Family B1008)

This was corroborated by care home staff participants:

'How do you know that families get enough information relayed to them as they should have? (Care home staff B3011)

Quantitative data supported these findings. IPOS-Dem assessments were completed in full for 21 out of 32 (65.6%) residents at baseline. Completion improved over time to 25 out of 30 (83.3%) complete assessments at final time point. Across all 28 items for 32 residents (896 items across all cases), IPOS-Dem had 19 (2.1%) missing items at baseline and this decreased to 9 (1.1%) for 30 residents (840 items across all cases) at the final time point. At baseline 14 out of the 28 IPOS-Dem items (50.0%) had no missing scores and this had increased to 21 out of 28 items (75.0%) at final time point (Table 2)

Table 2: IPOS-Dem scores at baseline (n=32) and final time point (n=30)

	Baseline					Final time point at 12 weeks				
IPOS-Dem item	**N**	**Missing N (%)**	**Cannot assess N (%)**	**Mean (SD)**	**Range**	**N**	**Missing N (%)**	**Cannot assess N (%)**	**Mean (SD)**	**Range**
Physical symptoms										
Pain	29	0 (0.0)	3 (9.4)	0.62 (0.82)	0-2	29	1 (3.3)	0 (0.0)	0.86 (0.92)	0-3
Shortness of Breath	31	1 (3.1)	0 (0.0)	0.23 (0.62)	0-2	29	1 (3.3)	0 (0.0)	0.17 (0.38)	0-1
Weakness or lack of energy	31	0 (0.0)	1 (3.1)	0.97 (1.08)	0-3	30	0 (0.0)	0 (0.0)	0.87 (1.0)	0-3
Nausea	30	0 (0.0)	2 (6.3)	0.13 (0.57)	0-3	30	0 (0.0)	0 (0.0)	0.33 (0.84)	0-3
Vomiting	31	1 (3.1)	0 (0.0)	0.13 (0.72)	0-4	30	0 (0.0)	0 (0.0)	0.20 (0.76)	0-3
Poor appetite	32	0 (0.0)	0 (0.0)	0.63 (0.75)	0-2	30	0 (0.0)	0 (0.0)	0.63 (0.85)	0-3
Constipation	30	0 (0.0)	2 (6.3)	0.37 (0.56)	0-2	30	0 (0.0)	0 (0.0)	0.30 (0.65)	0-3
Dental Problems	31	0 (0.0)	1 (3.1)	0.10 (0.30)	0-2	30	0 (0.0)	0 (0.0)	0.13 (0.43)	0-2
Sore or dry mouth	32	0 (0.0)	0 (0.0)	0.09 (0.39)	0-2	30	0 (0.0)	0 (0.0)	0.00 (0.00)	0-0
Drowsiness	32	0 (0.0)	0 (0.0)	0.84 (0.88)	0-3	30	0 (0.0)	0 (0.0)	0.70 (0.92)	0-3
Poor mobility	32	0 (0.0)	0 (0.0)	1.19 (1.36)	0-4	30	0 (0.0)	0 (0.0)	0.93 (1.26)	0-3
Swallowing problems	32	0 (0.0)	0 (0.0)	0.22 (0.71)	0-3	30	0 (0.0)	0 (0.0)	0.07 (0.25)	0-1
Skin breakdown	32	0 (0.0)	0 (0.0)	0.41 (0.71)	0-2	30	0 (0.0)	0 (0.0)	0.37(0.77)	0-3
Diarrhoea	32	0 (0.0)	0 (0.0)	0.13 (0.55)	0-3	30	0 (0.0)	0 (0.0)	0.13 (0.43)	0-2
Physical symptoms sub-score: no imputation (14 items)	25 22*	2 (0.5)$	9 (2.0)$	5.72 (4.92) 5.32 (4.38)*	0-18	28 22*	2 (0.5)$	0 (0.0)$	5.96 (4.99) 5.27 (4.36)*	0-19
Physical symptoms sub-score: imputation 1†	32	n/a	n/a	6.04 (4.63)	0-18	32	n/a	n/a	5.70 (4.76)	0-19
Physical symptoms sub-score: imputation 2‡	32 30*	n/a	n/a	6.12 (4.74) 5.69 (4.35)*	0-18	30	n/a	n/a	5.67 (4.94)	0-19
Emotional, social and existential concerns										
Difficulty communicating	32	0 (0.0)	0 (0.0)	1.09 (1.23)	0-4	30	0 (0.0)	0 (0.0)	0.97 (1.00)	0-3
Sleeping problems	31	1 (3.1)	0 (0.0)	0.13 (0.50)	0-2	28	0 (0.0)	2 (6.7)	0.07 (0.26)	0-1
Hallucinations and delusions	32	0 (0.0)	0 (0.0)	0.69 (1.06)	0-4	29	0 (0.0)	2 (6.7)	0.59 (0.91)	0-3
Agitation	32	0 (0.0)	0 (0.0)	1.50 (1.27)	0-4	30	0 (0.0)	0 (0.0)	0.77 (0.97)	0-3
Wandering	32	0 (0.0)	0 (0.0)	0.41 (0.62)	0-2	30	0 (0.0)	0 (0.0)	0.47 (0.78)	0-3
Anxious or worried	32	0 (0.0)	0 (0.0)	1.06 (1.19)	0-4	29	0 (0.0)	1 (3.3)	0.86 (0.79)	0-2
Depressed	30	1 (3.1)	1 (3.1)	0.80 (0.96)	0-4	30	0 (0.0)	0 (0.0)	0.53 (0.73)	0-2
Lost interest	31	0 (0.0)	1 (3.1)	1.39 (1.23)	0-4	30	0 (0.0)	0 (0.0)	1.03 (1.03)	0-3
Peace	31	0 (0.0)	1 (3.1)	1.00 (0.97)	0-4	30	0 (0.0)	0 (0.0)	0.83 (0.79)	0-3

	Baseline					Final time point at 12 weeks				
IPOS-Dem item	**N**	**Missing N (%)**	**Cannot assess N (%)**	**Mean (SD)**	**Range**	**N**	**Missing N (%)**	**Cannot assess N (%)**	**Mean (SD)**	**Range**
Positive interaction	32	0 (0.0)	0 (0.0)	0.94 (1.16)	0-4	30	0 (0.0)	0 (0.0)	1.30 (0.79)	0-3
Enjoyment of activities	32	0 (0.0)	0 (0.0)	1.53 (1.34)	0-4	30	0 (0.0)	0 (0.0)	1.20 (1.06)	0-4
Practical problems	31	1 (3.1)	0 (0.0)	0.23 (0.43)	0-1	30	0 (0.0)	0 (0.0)	0.17 (0.59)	0-3
ESE concerns mean sub-score: no imputation (12 items)	26	3 (0.8)$	3 (0.8)$	11.08 (7.91)	0-29	27	0 (0.0)$	5 (1.4)$	8.52 (5.91)	0-25
	21*			9.71 (6.90)*		21*			8.80 (6.47)*	
ESE concerns mean sub-score: imputation 1†	32	n/a	n/a	10.76 (7.17)	0-29	32	n/a	n/a	8.79 (5.48)	0-25
ESE concerns mean sub-score: imputation 2§	32	n/a	n/a	10.77 (7.18)	0-29	30	n/a	n/a	8.86 (5.71)	0-25
	30*			9.66 (5.86)*						
Family concerns										
Family anxious or worried	31	0 (0.0)	1 (3.1)	0.45 (0.89)	0-4	29	0 (0.0)	1 (3.3)	0.45 (0.74)	0-2
Family information	31	0 (0.0)	1 (3.1)	0.13 (0.34)	0-1	29	0 (0.0)	1 (3.3)	0.07 (0.26)	0-1
Family concerns sub-score: no imputation (2 items)	30	0 (0.0)$	2 (3.1) $	0.60 (1.04)	0-4	29	0 (0.0)$	2 (3.3)$	0.52 (0.87)	0-3
	27*			0.59 (1.05)*		27*			0.48 (0.85)*	
Family concerns sub-score: imputation 1†	32	n/a	n/a	0.58 (1.01)	0-4	32	n/a	n/a	0.52 (0.83)	0-3
Family concerns sub-score: imputation 2‡	32	n/a	n/a	0.56 (1.01)	0-4	29	n/a	n/a	0.52 (0.87)	0-3
	29*			0.55 (1.02)*						
Total scores										
Total score: no imputation (28 items)	21	5 (0.6)	14 (1.6)	18.14 (12.15)	0-44	25	2 (0.2)	7 (0.8)	14.56 (9.71)	0-42
	17*			15.47 (10.51)*		17*			15.82 (10.94)*	
Total score: imputation 1†	32	n/a	n/a	17.38 (10.39)	0-44	32	n/a	n/a	15.01 (9.05)	0-42
Total score: imputation 2‡	32	n/a	n/a	17.46 (10.46)	0-44	30	n/a	n/a	15.05 (9.44)	0-42
	30*			15.89 (8.70)*						

SD: standard deviation

* n= analysis for complete pairs only

$ Denominator is number of items in sub or total score multiplied by number of resident assessments

† Imputation 1: mean IPOS-Dem item score imputed

‡ Imputation 2: case mean item (sub)-score imputed

Missing data was either missing as it was rated as 'Cannot assess' by the care home staff, or items were not completed (i.e. reason unknown). At baseline 14 out of 896 (1.6%) items were rated 'cannot assess' and 5 out of 896 (0.6%) were missing with reasons unknown. 'Pain' had the highest number rated 'cannot assess' (n=3, 9.4%), followed by 'nausea' (n=2, 6.3%) and 'constipation' (n=2, 6.3%). At the final time point, 7 out of 840 (0.8%) were rated 'Cannot assess' and 2 out of 840 (0.2%) were missing with reasons unknown. 'Sleeping problems' and 'hallucinations and delusions' had the highest number rated 'Cannot assess' (n=2, 6.7%). We tested the null hypotheses that there is no relationship between missing IPOS-Dem items and dementia stage, agitation, function or care home; and were unable to reject any of the null hypotheses. It is likely that the missing data is related to some other unexplored factor such as a feature of care home staff.

Thirty out of 30 (100%) of care home staff who responded at baseline (two missing responses) reported that the time spent completing IPOS-Dem had been worthwhile compared to 20 out of 30 (66.7%) at final time point (no missing responses). At baseline 30 out of 31 (96.8) reported no challenges to completing IPOS-Dem (one missing response) and final time point 26 out of 28 (92.9%) reported no challenges to completing IPOS-Dem (two missing responses). The following two reasons for challenges were provided (one care home staff did not provide a reason): *'Sometimes difficult to know if resident in pain due to low moods', 'Don't know about family, don't know how to assess hallucination'.* At baseline 8 out of 31 (25.8%) (one missing response) of the care home staff reported that completing IPOS-Dem would result in changes to care. At final time point this had increased to 18 out of 30 (60.0%) (no missing responses).

Acceptability: comprehensiveness and relevance

Participants reported that the items of IPOS-Dem are relevant, comprehensive and important. Family participants in particular welcomed the comprehensive nature of the assessment:

'…so I think you know just the over the past week where you've got I think it's question 3 to – yes it's question 3 onwards you know about their, how they are, how they're feeling, and interacting with other people and staff and I think that's really really important. Lots of people do interact and I feel my mum doesn't, and my mum's always been a party girl you know she was always get up and go,…' (Family A3002)

And that it addressed important concerns, including their own:

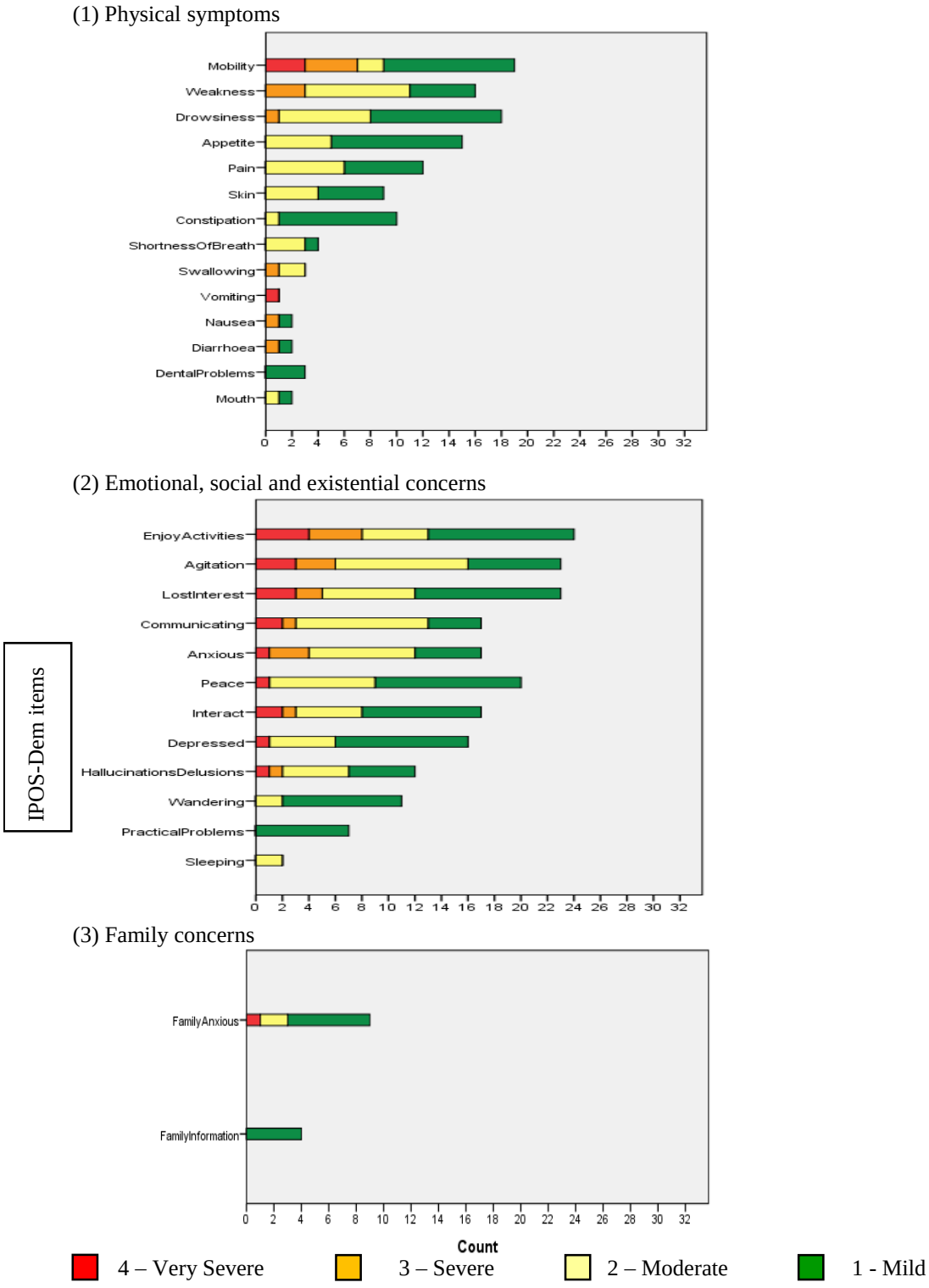
'Anxious, has any of her [family been], anxious or worried about the person, I think that's important really, I mean I think, [sigh] (Family A3003)

There was some discussion amongst family members about the acceptability of the term 'palliative care' with most, but not all participants finding the term acceptable and appropriate:

***'**but your mum's been in homes for 8 years so I wouldn't see her in the same sort of category, I wouldn't see her as having palliative care would you? (Family B3008) … but it is really, it is the end of her life, isn't it? (Family B3007) … yeah I suppose so (Family B3008) … it's how long they can hang on for (Family B3010) … I think it's also understanding that people do, as we said earlier, people do die from Alzheimer's you know it's not just a condition (Family B3007) … oh yeah (Family B3008) … they die from it (Family B3007)' (Family focus group)*

Fig 3 shows prevalence and severity of symptoms and concerns experienced by residents at baseline, by symptom and/or concern subgroups comprising: (1) physical symptoms, (2) emotional, social and existential (ESE) concerns, and (3) family concerns. ESE concerns were the most prevalent and severe with a mean item score of 0.90 (SD 0.60) compared to physical symptoms with a mean item score of 0.44 (SD 0.44) and family concerns with a mean score of 0.28 (SD 0.51). The full range of IPOS-Dem (0-4) scores for the majority of items were not used (Fig 3, Table 2). On question one (free text item), seven cases had three main problems reported, five cases had two main problems and eight cases had one main problem. The majority of these were classified as 'agitation' (n=11), followed by 'poor mobility' (n=4), 'anxious' (n=4), 'wandering' (n=4) and 'pain' (n=1). The remainder could not be classified into IPOS-Dem items as they were specific to the individual (S3 Table).

Fig 3: Prevalence and severity of (1) physical symptoms, (2) ESE concerns, and (3) family concerns (n=32)



There were no significant differences between baseline and final time points for mean total scores and the three symptom/concerns subgroups with or without imputation. Areas of physical symptoms and ESE concerns appeared to remain stable across the time points with moderate correlation between baseline and final time points with all imputations (rho= 0.58-0.80). Family concerns were not correlated (rho=0.25-0.29) between baseline and final time points.

Feasibility: brief and flexible use

All participants reported the usefulness of completing IPOS-Dem at baseline. In both phases, the majority of participants identified that IPOS-Dem should be used routinely when reviewing care plans and at times of change in resident presentation (e.g. changes in behaviour, unstable or deteriorating physical health), with a minority of participants stating that IPOS-Dem should only be used at baseline and at times of change to identify potential symptoms or problems that could be contributing to a changed presentation.

The majority of participants described its feasibility for use in routine care, as quick to complete, and that it became quicker to use over time. With few exceptions, professional participants reported that IPOS-Dem was best done monthly to inform care plans, but with flexibility and more frequently if required:

'For some people it might vary, some people you might need to do it every day (Care home staff C1007) … yeah (Manager C1005) …whereas some people you might do it once a month, while some you have to do it weekly (Care home staff C1007)

One manager considered the potential benefit and usefulness of IPOS-Dem being used on a weekly basis:

'Erm do I think you should tell people how to – how – I think if you don't give them a minimum timescale there will be those who will only use it when they know you need, they've got to, erm the thing with monthly which is, is only really coming to me as we're talking, the thing with monthly is it's only capturing one week in the month, but you can't capture a month in one tick box and I'm just thinking to be honest this would be so much easier for every staff to have one of these every Monday to fill in for the previous week or you know one day for the previous week on their key residents and then when they come to do their care plan they've got the information there' (Manager B3001.2)

Conversely, family participants expressed greater concern regarding the feasibility of IPOS-Dem and the potential time burden on care home staff and risk of taking from their caring role:

'I think, I mean I think what, what is always helpful if you have to do this kind of monitoring and tracking is for it to be as simplified as possible and that it can be incorporated in the work that [care home staff] do, … it's very difficult I think these kinds of monitoring and tracking systems are just simply time consuming and sometimes do take away from the business of you know communicating and doing all the basic stuff' (Family A3004)

The mean time it took to complete IPOS-Dem at baseline was 8.48 minutes (SD 4.98) and at final time point was 5.60 minutes (SD 1.45).

Validity and reliability; 'trusted assessment'

Participants in both phases identified the potential risk of inaccurate assessment, either as a result of poor assessment or the measurement properties of IPOS-Dem (i.e. reliability):

'… but to me poor appetite might be not eating for a week, for somebody else it is a different pers- they'll say poor appetite is when you haven't eaten for a couple of hours… (Family B1007)

As such, participants discussed whether IPOS-Dem would provide them with useful and trustworthy information, and the requirement for health care professionals to trust the assessment of care home staff. Participants identified that a measure that is recognised across agencies and trusted would evidence their assessment and support communication with visiting health care professionals. This would also address the challenge of integrated working:

'and they've got the time to do it honestly, truthfully, then yes because anyone that needs to look at this whether it be GP, ambulance, consultant, relative, they know exactly what is going on' (Family B3006)

Touchscreen technology

Use of touch-screen technology was identified by both family and professional participants as improving acceptability through improved ease of use, improved ease of monitoring, support in identifying areas of concerns and triggering action plans:

'Erm, it's a long way off but somebody's got to start planning it, and this would fit perfectly with that touchscreen situation, and if it was done in such a way that you could identify one particular aspect as well and just get the swallowing for the last 6 months or the skin integrity for the last 6 months it would be brilliant' (Manager B3001.1)

Implementation requirements

Managers and care home staff considered leadership as essential in implementing IPOS-Dem to facilitate integration into routine care processes through e.g. supervision, care planning. Leadership was seen as required to support adoption by all care home staff, ensuring that care home staff remember to use the measure, and ensuring they understand its purpose; thus ensuring that the measure is recognised as a valued tool to support care provision despite additional time burden:

'and I know it's more work, but even if it's only a little bit, it's still more work regardless of a little or a lot but I think things like this which, I don't mean this selfishly, doesn't just look after the clients, it promotes us, it promotes the care we're giving, it promotes the way in which we work, so you know, I don't think it shouldn't be done. I think it's something that all homes should do' (Manager C1005)

Care home staff identified challenges of remembering and getting into the routine of using IPOS-Dem on a monthly basis. Quantitative data supported this with the number of IPOS-Dem measures being completed increasing from zero (0.0%) in the first month to seven (23.3%) in the final month. Care home staff also identified the practical challenges of making IPOS-Dem accessible for family members and external health care professionals.

Care home staff participants overwhelmingly reported that IPOS-Dem was easy to use and did not feel that training was required. Senior care home staff and managers, however, stated that online training or DVD training would support implementation of the measure, and that this would be important to understand the potential benefit of IPOS-Dem and how it may support care.

Discussion

We found that it is possible to introduce a measure into the routine care of residents and that this may change care processes to improve resident and family outcomes. We identified likely mechanisms of action within the residential care home context taking into account multi-agency working between family members, care home staff and health care professionals. Important measurement properties both to facilitate its use and support mechanisms of action were identified; as well as the requirements for implementation. Based on our findings, we developed a theoretical model (Fig 2).

Our findings supported many of our expected mechanisms of action including improved observation and awareness, improved care planning and care provision, and facilitated communication and collaboration between all agencies; corroborating results of previous studies in clinical [18, 51, 52] and care home [53, 54] settings. We identified additional unexpected mechanisms of action reflecting the more complex care processes in residential care homes. The use of IPOS-Dem facilitated a comprehensive assessment of resident symptoms and concerns, which fostered a 'picture of the person'. This 'picture of the person' was valued as a means of recording complex assessments of residents in a succinct and easily accessible format, which in turn supported systematic records-keeping, monitoring, and improved knowledge of residents over time. Furthermore, the 'picture of the person' facilitated communication within care home settings, supporting a previous finding [53]. This included incorporating IPOS-Dem into supervision to monitor assessments and ensure that symptoms and concerns are acted upon. We identified challenges to communication between family members and care home staff. These resulted from care home staff confidence and skill, shift work and differing expectations of roles. IPOS-Dem was identified as a potentially useful tool to overcome some of these barriers, thus improving and empowering family engagement in care provision; important to family members [55]. In addition, the measure if trusted and recognised by both parties, could facilitate communication to external health care professionals. This is important as there are known challenges to integrated working between social and health care sectors [16] with barriers including a lack of trust between residential care homes and health care providers, and care home staff perceived lack of respect for their knowledge and skills [37, 56].

Participants reported that the measure was easy to use and provided value to care. Low missing data support this finding. However, qualitative and quantitative data suggest that there were challenges to assessing people who have difficulties expressing their wishes and concerns. All care home staff rated the time spent completing IPOS-Dem as worthwhile at baseline, which decreased at the final time point. The reason for this is unknown. However, it is possible that care home staff found the baseline assessment most useful, and that information subsequently obtained from IPOS-Dem was of less value as symptoms and concerns had already been identified. Conversely, care home staff ratings of whether using IPOS-Dem would change care processes increased from baseline to final time point. Again, while the reasons for this are not known, it is possible that over the course of the study, care home staff increasingly recognised the role of using IPOS-Dem to support care. We examined the use of IPOS-Dem without any support from the research team so as to understand its use and implementation without any additional resources, frequently unavailable. IPOS-Dem completion rates were low but continued to increase throughout the course of the implementation. Qualitative data suggest that care home staff required time to get into the routine of using and remembering to use IPOS-Dem, and put structures in place to support its use. This explains the low but increasing use of IPOS-Dem over the 12 week implementation period, and suggests that, with the right training resources, it might be possible to implement IPOS-Dem without the use of 'high facilitation' [36, 57].

Our participants identified the importance of the measure being comprehensive. This reflects the multiple symptoms and concerns that this population may experience due to dementia, multi-morbidities and side-effects of treatments [9]. Family members welcomed that their own concerns were considered in the assessment, corroborating the importance of family concerns [58]. Touchscreen technology, while not essential, was identified as a potential key facilitator in completing IPOS-Dem, storing records, monitoring over time and communication including online access for family members. This technology is becoming increasingly common in using measures in routine care [17] and may support implementation particularly if it facilitates measure completion, storing, retrieving and analysis of scores [59]. However, it is not yet widely used in UK care homes.

We found that leadership engagement at all phases was essential in implementing IPOS-Dem, corroborating existing evidence [59, 60]. Our findings support results of previous reviews of implementation interventions [16, 61], that interventions that take into consideration time pressures and facilitate conversations between care home staff and health care professionals, and those that utilise structured resources and/or tools, are more likely to be implemented and effective in improving outcomes.

In order to triangulate our data, we examined differences and similarities between family and professional participants. Family and professional participants identified similar mechanisms of action; and problems with communication although they expressed different perspectives and concerns. One surprising finding was the discrepancy between participant groups regarding the feasibility of using IPOS-Dem. Few professional participants expressed concern regarding feasibility with some considering the potential usefulness of using IPOS-Dem as frequently as weekly. Family participants, however, worried that care home staff may not have the motivation or time to use IPOS-Dem, and the potential for it detracting from their caring responsibilities.

Our study also gained an understanding of potential risk of harm of using a measure in routine care. No risks of causing harm to residents or family members were identified. However, participants did identify risks of inaccurate assessment either due to poor assessment or lack of measurement reliability, corroborating a finding of a previous study [53]. Another potential risk was that even if care home staff identified symptom or concerns, they may not act, or may struggle to obtain health services required [16]. Factors that mitigated these risks were good leadership, use of the measure in supervision, and implementation involving health care professionals external to the care home. Furthermore, collaborative working with family may empower family members to challenge assessment and act upon identified concerns.

Our findings indicate that further work is warranted. There are challenges to assessing people who have difficulties expressing their wishes and concerns. Training to support assessment particularly of the more challenging symptoms such as pain and hallucinations would improve acceptability. Our findings also suggest that a training component should incorporate information on the measure being ‘trusted’, how it can provide value to care, and how to support its integration

into care processes. Established validity and reliability is important and further psychometric testing is warranted. Finally, a larger feasibility trial is required to inform the research methods for a full trial to evaluate the effectiveness of IPOS-Dem in improving resident and family outcomes [19].

As with all studies, there are a number of strengths and limitations. Rather than just hypothesise the mechanisms of action pre-implementation, we examined the use of the measure during implementation into routine care, taking into consideration the residential care home context and implementation requirements. We incorporated family perspectives and compared and contrasted these to professionals thus gaining a much more detailed and insightful view into some of the contextual challenges and potential mechanisms of action. To triangulate our data, we used a number of different qualitative and quantitative data collection methods [48]. The limitations of the study are that the study settings are likely to be 'good' care homes and more receptive to implementing new initiatives. Our sample size of residents was small and there were challenges to identifying and recruiting family members. The implementation phase of the study was 12 weeks, which limits the understanding of implementation and integration into care processes, and long-term sustainment in routine care.

Conclusion

In a population with dementia and complex care needs, characterised by multi-morbidity and high symptom burden, and with challenges in assessment and integrated working; IPOS-Dem introduced into routine care is feasible and acceptable, and can support comprehensive and assessment and management of symptoms and concerns. The theoretical model developed conceptualises the likely mechanisms of action of how the measure may change care processes and potentially benefit residents and family members, and the implementation requirements. Further psychometric testing and a full trial of effectiveness are indicated.

Acknowledgements

The authors would like to thank all residents, family and staff for participation in the study; and all staff at the participating centres for support in recruiting and conducting the study. The authors thank South London and Maudsley NHS Foundation Trust Older Adults Service User and Carer Advisory Group (SUCAG), Gill Peters as an expert through experience, and Caty Pannell, research nurse for their contribution and study support. BuildCARE is supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy & Rehabilitation, UK. CI: Higginson. Grant leads: Higginson, McCrone, Normand, Lawlor, Meier, Morrison. Project Co-ordinator/PI: Daveson. Study arm PIs: Pantilat, Selman, Normand, Ryan, McQuillan, Morrison, Daveson. We thank all collaborators & advisors including service-users. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara A Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J Evans, Lesley Henson, Irene J Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Lara Klass, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Susan Molony, Sean Morrison, Fliss E Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Gao Wei.

References

1. Lee M, Chodosh J. Dementia and Life Expectancy: What Do We Know? J Am Med Dir Assoc. 2009;10:466-71. doi: 10.1016/j.jamda.2009.03.014.
2. Reisberg B. Functional assessment staging (FAST). Psychopharmacol Bull. 1988;24:653.
3. Harwood RH, Sayer AA, Hirschfeld M. Current and future worldwide prevalence of dependency, its relationship to total population, and dependency ratios. Bull World Health Organ. 2004;82:251-8. PubMed PMID: PMC2585969.
4. Bebbington A, Darton R, Netten A. Care Homes for Older people: Volume 2 admissions, needs and outcomes. The 1995/96 National Longitudinal Survey of Publicly-Funded Admissions: Personal Social Services Research Unit, University of Kent; 2001.

5. Mathillas J, Lövheim H, Gustafson Y. Increasing prevalence of dementia among very old people. Age Ageing. 2011;40:243-9. doi: 10.1093/ageing/afq173.

6. Etkind SN, Bone AE, Gomes B, Lovell N, Evans CJ, Higginson IJ, et al. How many people will need palliative care in 2040? Past trends, future projections and implications for services. BMC Med. 2017;15:102. doi: 10.1186/s12916-017-0860-2.

7. Mitchell SL, Teno JM, Kiely DK, Shaffer ML, Jones RN, Prigerson HG, et al. The clinical course of advanced dementia. N Engl J Med. 2009;361:1529-38.

8. Lyketsos CG, Lopez O, Jones B, Fitzpatrick AL, Breitner J, DeKosky S. Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment: Results from the cardiovascular health study. JAMA. 2002;288:1475-83.

9. National Institute for Health and Clinical Excellence. Multimorbidity: clinical assessment and management 2016. Available from: https://www.nice.org.uk/guidance/ng56/chapter/Recommendations.

10. Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. Br Med J. 2011;343:d4065.

11. National Institute for Health and Clinical Excellence/Social Care Institute for Excellence. Dementia: Supporting people with dementia and their carers in health and social care 2011. Available from: http://www.nice.org.uk/nicemedia/live/10998/30320/30320.pdf.

12. Hall S, Kolliakou A, Petkova H, Froggatt K, Higginson IJ. Interventions for improving palliative care for older people living in nursing care homes (review). Cochrane Database Syst Rev. 2011;(3):CD007132. doi:10.1002/14651858.CD007132.pub2.

13. Goodman C, Evans C, Wilcock J, Froggatt K, Drennan V, Sampson E, et al. End of life care for community dwelling older people with dementia: An integrated review. International Journal of Geriatric Psychiatry. 2010;25:329-37.

14. Ellis-Smith C, Evans CJ, Bone AE, Henson LA, Dzingina M, Kane PM, et al. Measures to assess commonly experienced symptoms for people with dementia in long-term care settings: a systematic review. BMC Med. 2016;14. doi: 10.1186/s12916-016-0582-x.

15. Murphy E, Froggatt K, Connolly S, O'Shea E, Sampson EL, Casey D, et al. Palliative care interventions in advanced dementia. Cochrane database of systematic reviews (Online). 2016;12:Cd011513. doi: 10.1002/14651858.CD011513.pub2.

16. Goodman C, Dening T, Gordon AL, Davies SL, Meyer J, Martin FC, et al. Effective health care for older people living and dying in care homes: a realist review. BMC Health Serv Res. 2016;16:1-14. doi: 10.1186/s12913-016-1493-4.

17. Etkind SN, Daveson BA, Kwok W, Witt J, Bausewein C, Higginson IJ, et al. Capture, Transfer, and Feedback of Patient-Centered Outcomes Data in Palliative Care Populations: Does It Make a Difference? A Systematic Review. J Pain Symptom Manage. 2015;49:611-24.

18. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM, et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. J Clin Oncol. 2004;22:714-24.

19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337(sep29_1):a1655-a.

20. Medical Research Council. A framework for development and evaluation of RCTs for complex interventions to improve health 2000. Available from: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372.

21. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350. doi: 10.1136/bmj.h1258.

22. Higginson IJ, Evans CJ, Grande G, Preston N, Morgan M, McCrone P, et al. Evaluating complex interventions in End of Life Care: the MORECare Statement on good practice generated by a synthesis of transparent expert consultations and systematic reviews. BMC Med. 2013;11:111.

23. Kupeli N, Leavey G, Moore K, Harrington J, Lord K, King M, et al. Context, mechanisms and outcomes in end of life care for people with advanced dementia. BMC Palliat Care. 2016;15:31. doi: 10.1186/s12904-016-0103-x.

24. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research. 2nd ed. Thousand Oaks, California: Sage Publications; 2011.

25. Slade M. Routine outcome assessment in mental health services. Psychol Med. 2002;32:1339-43.

26. Greenhalgh J, Long AF, Flynn R. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? Soc Sci Med. 2005;60:833-43.

27. Ellis-Smith C, Evans CJ, Murtagh FE, Henson LA, Firth AM, Higginson IJ, et al. Development of a caregiver-reported measure to support systematic assessment of people with dementia in long-term care: The Integrated Palliative care Outcome Scale for Dementia. Palliat Med. 2016 first published on October 25, 2016 doi:10.1177/0269216316675096.

28. Goodman C, Davies SL, Gordon AL, Meyer J, Dening T, Gladman JRF, et al. Relationships, Expertise, Incentives, and Governance: Supporting Care Home Residents' Access to Health Care. An Interview Study From England. J Am Med Dir Assoc. (0). doi: http://dx.doi.org/10.1016/j.jamda.2015.01.072.

29. Care Quality Commission. Care Quality Commission: Care homes 2016. Available from: http://www.cqc.org.uk/content/care-homes.

30. Mental Capacity Act. London: HMSO; 2005.

31. Gysels M, Evans CJ, Lewis P, Speck P, Benalia H, Preston NJ, et al. MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research. Palliat Med. 2013;27:908-17.

32. Goodman C, Baron NL, Machen I, Stevenson E, Evans C, Davies SL, et al. Culture, consent, costs and care homes: enabling older people with dementia to participate in research. Aging & mental health. 2011;15:475-81.

33. Schildmann EK, Groeneveld EI, Denzel J, Brown A, Bernhardt F, Bailey K, et al. Discovering the hidden benefits of cognitive interviewing in two languages: The first phase of a validation study of the Integrated Palliative care Outcome Scale. Palliat Med. 2016;30:599-610. doi: 10.1177/0269216315608348.

34. Cicely Saunders Institute. Palliative care Outcome Scale 2012. Available from: http://pos-pal.org/maix/.

35. Ellis-Smith C, Evans CJ, Higginson IJ, Pannell C, Henson LA, Daveson B. The content validity and utility of a screening tool to improve detection of problems, care provision and healthcare access for people with dementia in residential care homes: The Palliative care Outcome Scale for Dementia - Screening (POS-DemS). 14th World Congress of the

European Association for Palliative Care; 2016; Copenhagen, Denmark, May 2015: Palliative Medicine.

36. Kinley J, Stone L, Dewey M, Levy J, Stewart R, McCrone P, et al. The effect of using high facilitation when implementing the Gold Standards Framework in Care Homes programme: A cluster randomised controlled trial. Palliat Med. 2014;28:1099-109.
37. Davies S, Goodman C, Bunn F, Victor C, Dickinson A, Iliffe S, et al. A systematic review of integrated working between care homes and health care services. BMC Health Serv Res. 2011;11:320.
38. Morgan DL. Planning focus groups. The Focus Group Kit. Volume 2. Thousand Oaks, California: Sage Publications; 1998.
39. Bloor M, Frankland J, Thomas M, Robson K. Focus groups in social research. London: Sage Publications; 2001.
40. Microsoft. Microsoft: Microsoft office: Microsoft. Available from: https://www.microsoft.com/en-gb/.
41. Manthorpe J, Iliffe S, Samsi K, Cole L, Goodman C, Drennan V, et al. Dementia, dignity and quality of life: nursing practice and its dilemmas. Int J Older People Nurs. 2010;5:235-44.
42. Kerr C, Nixon A, Wild D. Assessing and demonstrating data saturation in qualitative inquiry supporting patient-reported outcomes research. Expert Rev Pharmacoecon Outcomes Res. 2010;10:269-81.
43. Sandelowski M. Sample size in qualitative research. Res Nurs Health. 1995;18:179-83.
44. Cohen-Mansfield J. Assessment of agitation. Int Psychogeriatr. 1996;8(2):233-45.
45. Mahoney RI, Barthel DW. Functional Evaluation: the Barthel Index (BI). Md State Med J. 1965:56-61.
46. QSR International. QSR International: Nvivo 10 for windows: QSR International Pty Ltd; 2014. Available from: http://www.qsrinternational.com/products_nvivo.aspxn (2014).
47. Hsieh H-F, Shannon S. Three approaches to qualitative content analysis. Qual Health Res. 2005;15:1277 - 88. doi:10.1177/1049732305276687.
48. Miles MB, Huberman AM, Saldana J. Qualitative Data Analysis: a methods sourcebook. Third ed. Thousand Oaks, California: Sage Publications; 2014.

49. Preston NJ, Fayers P, Walters SJ, Pilling M, Grande GE, Short V, et al. Recommendations for managing missing data, attrition and response shift in palliative and end-of-life care research: Part of the MORECare research method guidance on statistical issues. Palliat Med. 2013;27:899-907.

50. IBM Corp. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp; Released 2013.

51. Nicklasson M, Elfström ML, Olofson J, Bergman B. The impact of individual quality of life assessment on psychosocial attention in patients with chest malignancies: a randomized study. Support Care Cancer. 2013;21:87-95. doi: 10.1007/s00520-012-1496-6.

52. Detmar SB, Muller MJ, Schornagel JH, Wever LD, Aaronson NK. Health-related quality-of-life assessments and patient-physician communication. JAMA. 2002;288:3027-34.

53. Krumm N, Larkin P, Connolly M, Rode P, Elsner F. Improving dementia care in nursing homes: Experiences with a palliative care symptom-assessment tool (MIDOS). Int J Palliat Nurs. 2014;20:187-92.

54. Fuchs-Lacelle S, Hadjistavropoulos T, Lix L. Pain assessment as intervention: a study of older adults with severe dementia. Clin J Pain. 2008;24:697-707. doi: 10.1097/AJP.0b013e318172625a.

55. Hennings J, Froggatt K. The experiences of family caregivers of people with advanced dementia living in nursing homes, with a specific focus on spouses: A narrative literature review. Dementia. 2016. doi: 10.1177/1471301216671418.

56. Gage H, Dickinson A, Victor C, Williams P, Cheynel J, Davies SL, et al. Integrated working between residential care homes and primary care: a survey of care homes in England. BMC Geriatr. 2012;12:71.

57. Hockley J, Watson J, Oxenham D, Murray S. The integrated implementation of two end-of-life care tools in nursing care homes in the UK: an in-depth evaluation. Palliat Med. 2010;24:828-38.

58. Moyle W, Edwards H, Clinton M. Living with loss: dementia and the family caregiver. Aust J Adv Nurs. 2002;19:25-31. Epub 2002/05/11.

59. Antunes B, Harding R, Higginson IJ, on behalf of EUROIMPACT. Implementing patient-reported outcome measures in palliative care clinical practice: A systematic review of facilitators and barriers. Palliat Med. 2014; 28:158-75.

60. Dunckley M, Aspinal F, Addington-Hall JM, Hughes R, Higginson IJ. A research study to identify facilitators and barriers to outcome measure implementation. Int J Palliat Nurs. 2005;11:218-25.

61. Lund S, Richardson A, May C. Barriers to Advance Care Planning at the End of Life: An Explanatory Systematic Review of Implementation Studies. PLoS One. 2015;10(2):e0116629. doi: 10.1371/journal.pone.0116629.

Supporting information

S1 File. Fictional case vignettes (Appendix L)

S2 File. IPOS-Dem utility questionnaire

S1 Table. Qualitative participants' demographic data

S1 Fig. Flow diagram of resident participation

S2 Table. Model components with underpinning participant narratives

S3 Table. IPOS-Dem question one main problems

S2 File: IPOS-Dem utility questionnaire

Thank you for using IPOS-Dem today. In order for us to understand whether or not using IPOS-Dem is helpful and/ or practical when providing care, we would be grateful if you could answer the following questions. There are no right or wrong answers. The information you provide will help us know more about IPOS-Dem. We would be grateful if you complete this questionnaire each time you use IPOS-Dem.

You do not need to provide your name or any details about yourself. The research team collecting and analysing this information will not be able to identify who you are. If you have any questions or concerns about answering these questions, please feel free to contact [xxx] on the contact details below.

Please state approximately how long it has taken you to complete this questionnaire:

..... minutes

Will completing IPOS-Dem result in any action or changes to care, please circle:

YES / NO

Was the information obtained by completing IPOS-Dem worth the time spent, please circle

YES / NO

Did you encounter any challenges or problems using IPOS-Dem?

YES/ NO, please state .....

.....

.....

.....

.....

Thank you

S1 Table: Qualitative participants' demographic data

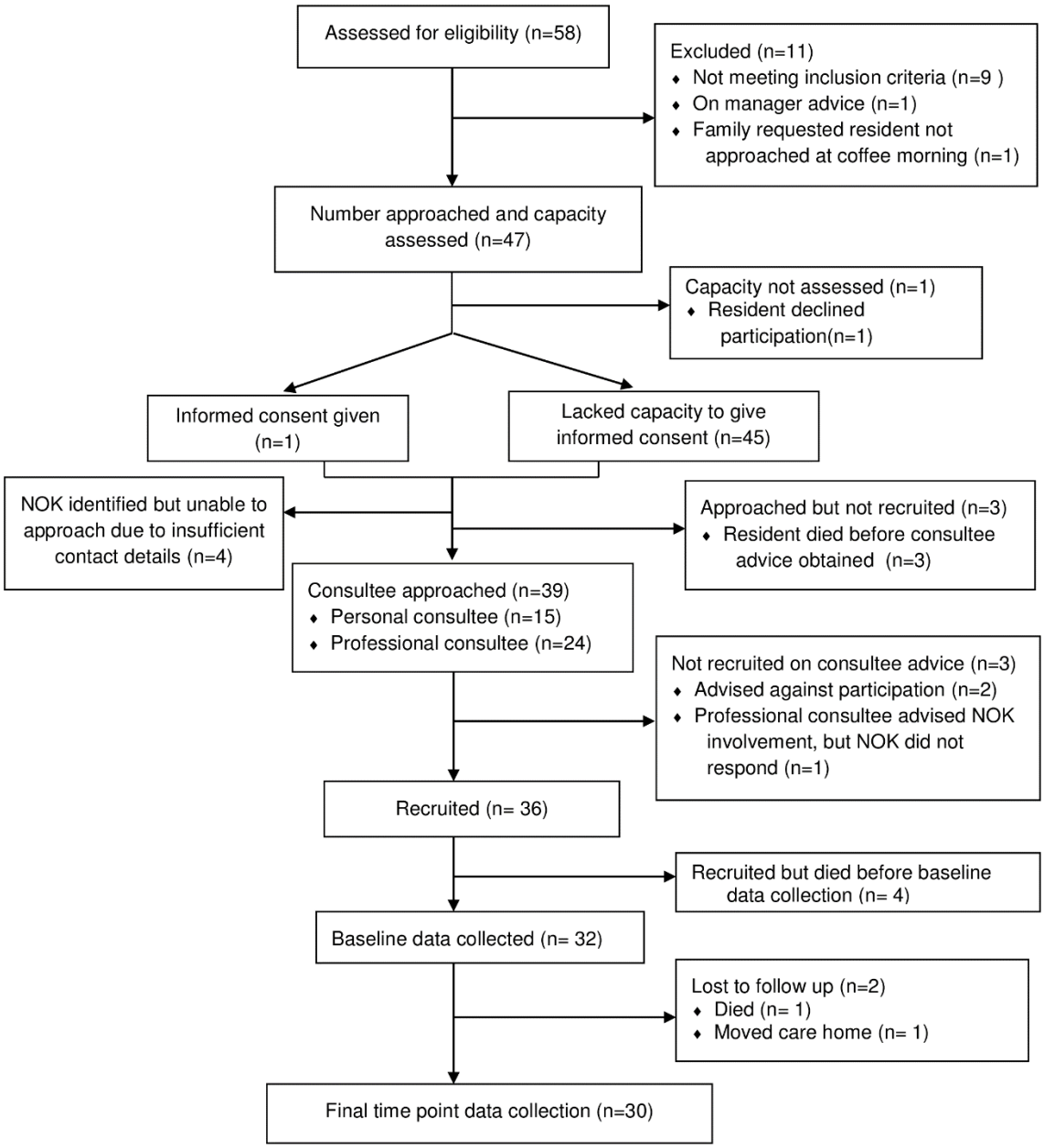
		Pre-implementation		**Post-implementation**	
Number of family participants		N=6		N=7	
Data collection	Method of data collection	Number of method types	Number of participants	Number of method types	Number of participants
	Focus group	1	3	1	5
	Interview	2	3	2	2
Age	Mean (SD)	60.5 (6.1)		63.7† (7.4†)	
	Median (range)	61.0 (53-68)		62.5† (57-78†)	
Sex	Male	1		2	
	Female	5		5	
Relationship to resident	Daughter	4		4	
	Son	1		1	
	Sister	n/a		1	
	Son-in-law	n/a		1	
	Friend	1		n/a	
Care home	Care home A	2		2	
	Care home B	3		5	
	Care home C	1		n/a	
Number of professional participants		N=20		N=11	
Data collection	Method of data collection	Number of method types	Number of participants	Number of method types	Number of participants
	Focus group	3	18	1	4
	Interview	1	2	1	1
	Manager interview	n/a	n/a	4	2
	Observation	n/a	n/a	3	4
Sex	Male	2		2	
	Female	18		9	
Profession	Role/ profession	Type of data collection	Number of participants	Type of data collection	Number of participants
	Manager	Focus group	2	Focus group	n/a
		Interview	1	Interview	2
	Team leader	Interview	1	Interview	1
				Observation	1
	Senior carer	Focus group	2	Focus group	0
				Observation	2
	Care assistant	Focus group	7	Focus group	4
	Activities	Focus group	2	Focus group	0
	coordinator	Focus group	3	Focus group	0
	GP			Observation	1
		Focus group	2	Focus group	0
	District nurse			Observation	0
Ethnicity	White British	8		4	
	White Irish	1		0	
	Indian	1		0	
	Black Caribbean	4		3	
	Black African	5		1	
	Black British	1		0	
	Missing	0		3	
Years of experience	Mean (SD)	10.3 (8.8)		18.2 (10.7)*	
	Median (Range)	7.0 (1-29)		19.0 (1.5-30)*	
Care home	Care home A	7		2	
	Care home B	6		9	
	Care home C	7		n/a	

SD: standard deviation

* Missing data for three participants

† Missing data for one participant

S1 Fig.: Flow diagram of resident participation



S2 Table: Model components with underpinning participant narratives

	Family	Professional
Action directly resulting from measure completion		
Improved observation and awareness of symptoms and concerns	**Pre-implementation**	
	'that would be quite difficult for me because if I visit once a week, I don't know whether she's been in pain' (Family B1009)	*'It might help to exclude other things, like you'd go through it and try to find out whether she's breathless, whether she's sick or vomiting, sort of a symptom checker list really?' (GP A1002)* *'I think it's interesting because in my head I'm thinking, well these are the thing we would do, you know if somebody became distressed, the first thing we'd say is are you in any pain? Are you… you know, so in a sense there it's a good way of, of making you think about the questions to ask, you as opposed to, um just assuming you've asked all the questions' (Manager B1005)*
	Post-implementation	
	'and I think this is a really good learning tool, this is what we're looking for, this is the sort of thing that will affect people erm and some people will already know this, they will have sort of walked in maybe having already had erm, erm experience with dementia and they will know this; but most people need it breaking down and so I think the fact that it's broken down into this level of detail must be really useful when you're starting to work in the care environment but I, I imagine that some of the people who are, who have worked there for many years probably could recount this in their sleep, erm and to actually have to constantly reiterate it would be diffi – more difficult … it's still time when you could be interacting with residents' (Family A3004) *'It makes you aware of things you, you know there's so much to do in your job that when you're focused on something you think actually she isn't, you now she isn't eating very well, she does leave her dinner every day whereas you know you're in such a rush to give out the dinners, collect them in and, and move them back into their seats they may not…' (Family A3002)* *'…but I don't know how much training they have in order to become a care worker and so it*	*'We understood the questions but I think you have to think deeply about what may be the answer you might think of. As a resident, as an individual maybe you don't quite think quite so deeply until someone asks you that question' (Care home staff B3011)* *'…or if it's not any changes for the, the client you are dealing with that would be easy but if it's a change that the person has um change then you have to be careful the way you are filling with not just to tick and tick and – (Care home staff B3014)* *'I think maybe we don't, you don't always think really a lot about people being at peace do you until the question's until you're asked that question' (Care home staff B3011)*

	Family	Professional
	doesn't become part of you really so maybe, you know and I think ongoing training and prompts like a questionnaire that just make you think' (Family A3002)	
Collaborative assessment between family members and care home staff and between all care home staff	**Pre-implementation**	
	'Isn't this where we come in? As much as we can obviously give some history as to how our parents or whoever it is, um what their personality was, you know, and so we can contribute and say that prior to the diagnosis of dementia they were a difficult person anyway' (Family B1009)	
	Post-implementation	
		'Particularly if someone's sitting near to somebody else when they're completing it and they might just say 'what do you think about this?' so it's actually prompting conversation which maybe in some senses you're saying the document is meant to be really clear but as a care manager, I think it's brilliant that anything that prompts conversation between staff about a resident' (Manager B3001.1) *'I think sometimes it helps to know more about their past which you don't always know about, know what they've done within their life you know because sometimes that can, be a good thing to know you know sometimes when someone's passed away you've suddenly found out more about them when they've passed away than when they were here' (Care home staff B3011)*
Change in care processes		
Comprehensive 'picture of the person'	**Pre-implementation**	
	'Has [resident] been feeling anxious or worried? She does all the time, sometimes when this happens, sometimes when that happens. You can gauge a lot more from that than from one tick box' (Family A1006)	*'It doesn't actually tell us anything does it? Staff go on the care plan and they can, for staff going to the care plan they can read actually what has happened' (Manager A1009)*
	Post-implementation	
	'Well I mean it does look um nicely detailed, it looks like um I, what I imagine, um in terms of my own smaller capacity as carer, I um obviously do notice things about my mum and ask her questions and try and facilitate um information from her about how she's feeling um but to actually have it detailed in this way with particular criteria must be very useful I would think for the care workers, um and for me as well as I'm looking through it, it seems very sensible and very relevant so yes I think it's, I think it is a useful tool	*'Erm it sort of put you in the mind of, although we're doing care plans and we're doing report but it gives you a picture as well you know that you, you're seeing a picture of a person when you're doing this so yeah it do helps (Care home staff A3003)* *'Okay, but nobody ever sits down and thinks, well I say nobody ever, that's not true because they do but it would be so easy to say oh they just suffer with a sore mouth. What's the link between oh they're suffering with a sore mouth but actually they've got quite a lot of pain and they've been vomiting, have they got something that's*

	Family	**Professional**
	just to concentrate the mind really (Family A3004) *'Erm but I think if, if they had something like this where they you know, where the question is about informing, I think that would be helpful' (Family A3002)* *'Yeah I think that's really important um yes I mean I think all of those things are really important because I think definitely if there was anything, if any of these um came out negatively I know that my mum would be quite unwell and unhappy (Family A3004)*	*linking those 2 together, you know (Manager B3001.1)*
Systematic record-keeping	**Pre-implementation**	
		'I think you should do it regardless of the change, because then it's all documented isn't it? Because you want to have the documentation of the good changes as well as the bad changes' (Manager C1005)
	Post-implementation	
		'Okay so say for instance, let's go with the skin broken down. For weeks now Mrs So and So's skin broken down, you've got a variance, you've got it's changed, "not at all" to "moderately". The moment you have something that maybe goes over 2 boxes, page so and so this is what we did … almost like yeah so you're evidencing you've seen the change and you've actioned something' (Manager B3001.2).
Improved review and monitoring of symptoms and concerns	**Post-implementation**	
	'Well I think um I, I'm looking at some of the um the problems that are identified, I imagine that a lot of these things happen occasionally anyway, I mean everybody probably does have sort of sleep problems and diarrhoea and vomiting or whatever from time to time because you know we're human, but I suppose the important thing is, is to make sure that it's monitored and that that monitoring, that the number of times things happen might, might erm alert people to when there is a real problem…' (Family A3004)	*'or that would help them towards the end of life though because all that information you've got about that person could be used … yeah because if they suffer from depression or they're particularly low or there's different things you know about that person when it comes to the end of life you'd have more of an understanding about whether they're in pain or… (Care home staff B3011).* *'Well no in the sense that having copies whether we would have access or having copies that is what I'm asking because at times these are important when you are just you know to refresh the brain about what you've just you know something (Care home staff B3012)* *'I think what is interesting is it is making staff think because this constant question over the last week, over the last week and it's making staff think about a time span*

	Family	Professional
		rather than in the moment' (Manager B3001.1)
Care planning and timely changes to care provision	**Pre-implementation**	
		'And indeed [care home staff] using it to be an additional either reinforcement or even a step beyond, um and then to get into especially towards the end of life, and it does mean anticipating, it does mean early identification and action…' (GP B1004) *'… but it's not enough to say that that person's in pain. The minute you know that you have a responsibility and I suppose this is exactly the same. Is this person constipated? Yes. How often? Frequently. What are you going to do about it?' (Manager B1005)* *'Yeah I mean I think it could help the care plans because I think, because everything's got to coincide doesn't it, so there's no point the care plan saying that you know someone's fine, but this is saying that they're not' (Manager C1005)*
	Post-implementation	
	'that's right so some way of dragging together the bits that are more worrying than other bits, putting them together into a co – what do you call them and email in sort of data terms but you know putting the data together and creating an answer which says, you know there's a red light on this, you know giving red, orange and green lights really you know that patient or that care, or that care patient has got red lights we've got to keep an eye on him or her, she's green she's fine, she's okay at the moment, that's really the …' (Family B3008) *'I think, I think they yeah they would be more aware that is something they should be doing' (Family A3002)*	*'You know if we are because we're in the situation where we're thinking everybody's exactly the same and then suddenly the data comes back saying actually you aren't identifying that there have been quite significant changes which are written down but nobody's doing anything about. Because the problem with care plans is you write things down but you don't necessarily act on them' (Manager B3001.1)* *'and as I said again to me um a method like this helps um for us to go through and see if these people needed more help from outside agents more than you know so um so yeah so that would be a part of we supervising to see what staff are putting in and see if we needed more help from outside' (Care home staff A3003)* *'Um, just what I've said you know their changes would be identified and um we could act upon it' (Manager A3001.1)* *'I think this would help us write the care plan much better' (Care home staff B3013)* *'mhmm, staff have expressed that it's quite easy to use, which is good and that it doesn't take them too long erm because they're not having to actually write sentences, so they've found it useful in as much as they've done this and then they've gone to the longer care plan, using this so,*

	Family	**Professional**
		for instance if it's, if somebody doesn't normally have any pain and on this they've put that they've, you know they've got slight pain, it's given them the thing to say what is going on that's changed so it, it's sitting with the longer care plans but it's prompting the longer care plans to rather than just say no change, no change, everything's the same, it's now making them think about the individual questions so that's been quite helpful' (Manager B3001.2) *'well if we think people are getting very high scores, especially in pains and erm stuff we'd seek help from the doctors that obviously this person needs to be medicated for painkillers or you know um if it's anything to do with their mental stages deteriorating then it help us to get in touch more with the erm mental health team so…' (Care home staff A3003)* *'Yeah I do think so, I think looking back at these tools can you know if staff do it because sometimes they might not report straight away, I know they do report but if you go, if we go though and look and think oh but we missed this, this person could get more help, then yeah we could look at it and seek help from, from just what we're looking at I mean you do have staff that will discuss with their one another and they might not come in and say to us but if we look here and there's, you know they're thinking and doing it then we can look at it and think this person's score is quite high and sometime again some people in here not recognises dementia and if you look back at this you can see you know we should seek help for this person, something else might help them to be more settled and you know' (Care home staff A3003)* *'I think you know the more I've thought about it today the more I've thought about it being a weekly tool and I do think it triggers the mind and once it triggers the mind it triggers the care' (Manager B3001.2)* *'and as I said again to me um a method like this helps um for us to go through and see if these people needed more help from outside agents more than you know so um so yeah so that would be a part of we supervising to*

	Family	Professional
		see what staff are putting in and see if we needed more help from outside' (Care home staff A3003) *'I don't think so, not with the staff that are doing, that are doing it I think they're fairly confident and they, they feel sort of like fairly assured as to how to do it so I don't think that is an issue, and one of the other things that's come up is with the care plan that they write, they're writing about how the person is, but this always asks them to look back over the last week' (Manager B3001.2)* *'It will, won't it because you'll have a better understanding of that person and will have thought more about that individual, you know, and about their health and about their wellbeing so if you're more aware about that person, individual you should be able to treat them, treat them you know the way they need to be' (Care home staff B3011)*
Facilitated communication and collaboration between family members and care home staff	**Pre-implementation**	
	'If the staff were completing this on a weekly basis, can I come down and say, can I see what [they've] said about my mum? (Family A1006) … So would that be useful? (CES) …Oh God, yes (Family A1006) …Yeah (Family A1007)' *'I've also had slight problems in that when I want information it's often not readily available' (Family C1008)* *'and it has been a problem so often I've just, if I've needed something I'll ask her a question and give them an hour to try and look for it or a day. Um again this was about nobody to ask. If you go in there quite a bit at weekends, then you've got weekend staff who just say I don't know' (Family C1008)* *'Yeah, yeah because it's a two way – it should be a two way street it shouldn't all be left to the care home people and it shouldn't all be left to us – if we work hand in hand you'll get along better. That's an ideal though isn't it? Doesn't always work (Family A1006)*	
	Post-implementation	
	'… I'm sure there is a record on my mum but even when I, you know I	*'One has to be very um polite see, in a case like that it's crucial and one has to be very*

	Family	Professional
	meet with them they don't get it out and look at it you know, erm and I have said before now I'd like to come in and talk to you about her but they just say oh she's taking all her tablets and …' (Family A3002) *'I think you know I think anyone who's looking after your parents have to be, have to be engaged, very engaged with you and have to be very honest with you and you have to be very honest with them really' (Family A3004).* *'Erm some time ago and it was kind of 6 weeks and she still hadn't seen the doctor so I said I would take her, and then the doctor said that they couldn't see me and that they would come to the home but the home had to ring them and – and eventually the doctor came but they never even fed back to me what was going on' (Family A3002)* *'Communica – I can't fault this home at all for its care because I know that he's washed, fed, and looked after generally but erm [Manager] knows this because I've complained to [Manager], the communication here is terrible' (Family B3006)* *'I'd have to say it doesn't happen at all, they would probably say they do inform us but I, I just, I just come in, see my mum and just believe that everything else is a big black hole because when I ask questions I don't get answers' (Family A3002)* *'know that that's the truth and it's not the right thing to do and I know it isn't and here I look and I think she gets her tablets on time, she erm is clean, and dressed well, she err has good food, they keep the place you know quite clean erm and she can't get out so she's safe, erm and you can't have everything so there are lots of good things but I think communication is probably the biggest concern I have' (Family A3002)* *'I have trouble on the phone as well when I've phoned up to see how it is,*	*aware of the kind of information (Care home staff B3012)…information you give (Care home staff B3014) … how you give it and what you're going to say, some are sensitive so it's a very difficult (Care home staff B3012)…especially if someone's at the end of life' (Care home staff B3011)* *'One of the things that really frustrates me is when staff say well speak to the manager – no you're looking after the person, you tell them, and with this tool you can' (Manager B3001.2)* *'but maybe with this [IPOS-Dem] they don't have to go because some of them can't be bothered to sit there all, going through the care plan, where this you could just say okay we're using this now, as well as a care plan, if you don't have time to go through, look through this and you can see why we're saying that your dad or your mum needed more support you know so then they can look through and see what we're going on about (Care home staff A3003)* *'but you can always look through and you could always say to them if you not agree with what we've said in here then, with all means you could see a different picture from what we see because we are looking here looking after mum or dad, you could come in and see something else that we've missed so yeah you know so we could always say if you think that something I should add in then let us know and we could improve from that as well' (Care home staff A3003)* *'It depends on the kind of questions the relatives want to find out, is depends of the, the, the question, if it's the question that you can refer the person to the manager you refer the person to the manager, you have to limit what you can tell the family, sometimes you are keyworker for so so so person, when you are key worker the relative walk out and ask you oh how my mum has been, sometimes they will ask oh who is so so so person who look after my mum, if you are not there or if you are there they will come and call you say how my mum has been, has she been okay? So you say oh yeah yeah yeah she has been fine but with the question sometimes is the things that if she want to find more, you refer the person to the manager' (Care home staff B3014)*

	Family	Professional
	you never get, I know obviously they do shift and the shift patterns change' (Family B3006) *'but I find anything to do with record keeping is done very hastily on the hoof so you're just about to go out the door and someone says well will you sign this?' (Family B3007)* *'... but as I say it is always n, in a rush that you get pushed a piece of paper for you to sign and you really haven't got time to look through it' (Family B3007)* *'I must say I've, I haven't found it like you, I do a lot of emailing and I find that if I email and ask something, I get a response reasonably quickly back, I don't know whether you use email do you to contact [Manager]?' (Family B3008)* *'Well erm yeah I mean I think that, I think that er obviously the information, all the information that um they can give me about what's happening with my mum is really helpful, um I spend quite a lot of time with mum, she comes out here most Sundays for lunch, I take her out quite a lot walking so anything, I need to know what's, how she is at any particular time whether I can take her out, whether she can erm whether she can come erm with me anywhere, erm and how she's going to be so clearly I think it's, the more information that staff can give me about her physical and mental wellbeing the more I'm able to make the time that we have together erm happy' (Family A3003)* *'Erm but I think if, if they had something like this where they you know, where the question is about informing, I think that would be helpful' (Family A3002)* *'see I think it should be the other way around, I don't think that we should be thinking, are we embarrassed to ask, I think they*	*'Especially end of life if you're in that situation where somebody's seriously ill or it's kind of, and they're asking you like really explicit questions about that person you've got to know (Care home staff B3011) ... what to say (Care home staff B3013) ... you're telling the correction information because that, that could be you that's not (Care home staff B3011)'* *'So you have to think seriously (Care home staff B3011) ... especially if the resident um not well, and going to the hospital and the relative is there (Care home staff B3013) ... mm (CES) ... you are just trying to be cautious you don't want to say something that, it might affect you later on (Care home staff B3013) ... do not know (Care home staff B3014) ... or you don't know for sure (Care home staff B3013) ... you might upset them by saying something (Care home staff B3011) ... and then you might upset them by saying something so sometimes it's best for them to talk and you listen and if there's something you can say but say it in a very nice way (Care home staff B3013)'* *'You don't know, you don't have a clue, you have to go and look for team leader to tell the team leader that such and such person wants to know about – (Care home staff B3013) ...we're in a bit of an awkward situation sometimes (Care home staff B3011)'* *'I've got some relatives who will never leave the building without coming to speak to me, even though I know they've had a conversation with somebody else' (Manager B3001.2)* *'Do you think that such a tool could support working with family members? (CES) No they, they're not around enough really to um have an objective view on it' (Manager A3001.1)* *'Erm the risk for family members is that they will misunderstand the document erm and they will think that because it's got a tick that's the end of the answer, do you know what I mean? So there has to be open two way conversations. If a family member sees it they've got to be able to ask the questions, you can't be defensive with a document like this, you've got to be able to*

	Family	Professional
	should be saying please look at the record, please have a look at it, I think that, that the emphasis of this tool should in writing be on it, this tool should be made available on a regular basis to the family, so it should be pushed from them, not, we shouldn't feel ohh, I don't know whether we should ask or not, it's not the point, it's the other way around, the, the um, the home should be pushing the information to us and saying you're part of this, this journey, you must be with us all the way, it's not a matter of them providing it all and we just observing, you know we are part of the journey' (Family B3008)	*justify why you've written what you've written' (Manager B3001.1)* *'Yes, yeah you, if you want to fill up and you can, ever you want the family to be there and you see this is what your mother has been going through, she has been vomiting, I know you are aware of this that's why I'm putting it down, you can be agree, she's agree and you agree what you are doing it's nothing to hide from the family, have to share' (Care home staff B3014)* *'No I think the thing is you're absolutely right because some staff the moment they're challenged see it as an attack and go into defence, whereas I, I work really hard with staff to say this is a question, they're showing an interest in the person that you've been looking after, qualify your answer, tell them why you've done that, explain to them why you feel this, so instead of being all defensive what's it got to do with them, it's got everything to do with them erm and you need to be able to tell them how the money that their mum is paying for you to look after them is being spent wisely, qualify what you've done, you know' (Manager B3001.1)*
Facilitated communication between care home staff	**Post-implementation**	
		'I've had more staff come to me regarding 2 residents having difficulty swallowing in the last 2 months than I think I've had in the last 2 years all of a sudden erm I don't think she's swallowing properly, I think she's holding it in her mouth…' (Manager B3001.1) *'supervising [junior care home staff]to see that they are actually knowing the clients that they're looking after' (Care home staff A3003)* *'… and certainly one of the things I've considered is if somebody's been on annual leave saying to them make sure you read the [IPOS-Dem]. I haven't done it yet, but almost like on your first day back, the first thing you've got to, the thing you've got to achieve before the end of your first day is read – is just checking on every resident and you can't do that with the normal care plans but I think you could do it with this' (Manager B3001.2)* *'You notice that the person have erm that problem you have to report this to the senior care to the senior, then the senior*

	Family	Professional
		will come and look, if it's nothing that the home can deal with they have to call um…' (Care home staff B3014) 'GP' (Care home staff B3013) '…the doctor or emergency if it's um…' (Care home staff B3014) *'…because we have supervision with staff every six weeks so we will ask them about their residents so if we've got this document I noticed over the last couple of months you've noticed this what have you done about it? How have you identified it?' (Manager B3001.2)* *'or you can leave one of your colleagues you rely on to be observing the keyworker – the resident you know to see if there is anything important or necessary to say or to note about' (Care home staff B3012)*
Facilitated communication between care home staff and external health care professionals	**Pre-implementation**	
		'yeah, yeah I'd glance at it particularly, mainly to see if they noted any changes from what is usual for them, that might be helpful' (GP A1002) *'Another reason I'm saying that is that sometimes you have clients and you notice changes in them you're not quite sure what it is and you send them to the hospital and they send them back to us saying there's absolutely nothing wrong with them whereas if you send this they can see why you've thought there's something wrong' (Manager C1005)*
	Post-implementation	
	'The real issue is whether I suppose in a way maybe the other thing to think about is whether there should be some trigger so that the care workers refer forms which they think the GP should see, to the GP so that they do the sifting because the GP won't do it for sure, I mean you give him a pile of forms like this he'll say forget it. Um but if the carers say well there's 2 forms here that we think you should look at because this lady's had diarrhoea and then you know been vomiting and that kind of stuff' (Family B3008) *'Oh yeah, yeah and because if they want to say this has been happening, and they can look back on their notes and say actually you know it was noted that you know for the last 4 times we've filled this form in that she's had diarrhoea and so it would be a useful tool for … and being able to look at symptoms in order for the*	*'Absolutely no consistency and I don't know if that is nationwide or whether that's just London, but London is dreadful at the moment erm and so you can train one batch of district nurses and then next lot are going to come in in a month's time and don't know what it is you're talking about so it is going to be tough, it is going to be really really tough but if it became an, a nationally recognised tool then it wouldn't matter which [Clinical Commissioning Group] you work from this would be the thing, and it also says well this is what we've been assessing so we can say to the district nurse who says you know how long's this pressure area been there? Well actually this tool was done last week and there was no pressure area last week, so before you start screaming that it's been going for months and nobody's done anything, you know' (Manager B3001.1)* *'No I think it can be helpful as well you know for the doctor come in and you're quite busy you can say just look through this*

	Family	**Professional**
	doctor to work out what's wrong' (Family A3002) *'but this form is exactly what a GP would want to know isn't it, it's exactly what a GP would ask' (Family B3008)* *'Would there be any way of having a small front sheet that if there was any information that the home felt they needed, felt a doctor needed to know just put on it rather than him ploughing through it just put please see..?' (Family B3010)*	*in the meantime, I'm doing something and you'll see what I'm trying to say about the dementia, especially if the mental health team come in and we want to give them a picture of what's going on with this person then you could show them this and you know instead of sit there and explaining again they have that, they just go though and then they can ask you any question they want from it so' (Care home staff A3003)* *'um possibly if we contacted the mental health team um because we were concerned about certain changes in a resident's behaviour and they might say oh well monitor them for a few days and document the changes, I think this would be an ideal tool to use to do that' (Manager A3001.2)* *'No they wouldn't go to the doctor oh look doctor so and s, so and so but they might say oh [GP name] can you go and see so and so because, and it's just information they've got there because they've seen it' (Manager B3001.2)* *'Not our business, erm when you get down to hallucinations, agitation and wandering then if this is a change, if somebody, if we've been saying for the last 6 months that somebody's hallucinating severely, it actually says why didn't you get in touch with us sooner, but it also says we've been monitoring to make sure it wasn't a one off, and we can evidence that they have been hallucinating, that they have, I probably wouldn't wait 6 months but, you know but just for explanations sake. So it is a way of saying this is, this isn't new or this is new, this person never hallucinates and all of a sudden they are hallucinating, erm so yeah and you know we in [borough name] we use the care home interim, the care home support team' (Manager B300.1.)* *'Well I think um we have the booklet during this so there's a lot of information from the booklet, um and also yeah this will help as well for the, the professionals to see and work from it as well to see you know because they could come in and you'll miss something to tell them and if you have it all written down by the time they get here it's already here so it's um' (Care home staff A3003)*

	Family	Professional
		'I don't think it's worth doing on top of the care plan I mean you have sometimes you call the mental health team out and then they don't shuffle through those things if they have something like this' (Care home staff A3003) *'I think, I don't think they use the document to communicate in as much as I don't think they show [GP name] the document but I think it informs so if the staff are noticing something they'll mention it to the team leader and the team leader will then put them down to see the doctor' (Manager B3001.2)*
Resident and family member benefit		
Improved symptom management	**Post-implementation**	
		'Yeah I mean I can certainly think of one resident who erm has recently started to suffer with constipation and that was highlighted in this and now they're on a laxative which you know so I know this was used for that so – ' (Manager B3001.2)
Improved care of comprehensive emotional, social and existential concerns	**Pre-implementation**	
		'Because if you're finding things out from this and you're making the lives of clients better, whether it be in a health way, or whether it be mentally, physically, in whatever way, then that's a good thing, something you might not have picked up on without this' (Manager C1005)
	Post-implementation	
		'Because it does make you stop and think and it makes you stop and ask yourself what am I doing? What am I doing, what have I done about this and I think the minute you see there's a change and you see I've got to do something, that improves the life of a resident' (Manager B3001.2)
Increased family empowerment and engagement in care	**Post-implementation**	
	'Erm yeah I do because if maybe she had diarrhoea for - then I could possibly pick up on it you know and say to them have you done anything about this?' (Family A3002) *'[sighs] I think some family members could, yes, I do I think as a whole family members could question it, it might make them think a bit more and I could just imagine I wouldn't, I might not say anything because I'm that sort of person, I think I give up so, and I shouldn't, someone said something was done in the hospital recently, when I went to the hospital this week and someone said well didn't you say and I thought what's the point, if they're*	*'Yeah it might be reassuring to them that you know we are watching because they might have noticed a change and you know it would be reassuring for them to see oh yeah they've realised too and they're watching what's going on' (Manager A3001.2)*

	Family	Professional
	in that profession and they don't see that, you know my mum was supposed to be keeping this thing on her eye and she kept moving it and she went "put it back", and you think don't talk to her like that, but I thought, if, if I have to tell you then you're not going to change you know what's the point in having an argument you know with someone and I think maybe I don't speak up when I should at times, you know and I think if this, if they ticked that they'd communicated with me, I think there's a chance I might not say anything (Family A3002) *'I think the staff could press more for the visitors to have a look at the tool and even perhaps a comment on it because that would help them to sort of respond to anything that the staff had spotted so I think that, I think that you know the danger of this kind of form filling is that it just gets put away and everybody thinks thank God I've filled in a form, that's it you know finished, but it's no good unless it's actually a positive err useful piece of work really isn't it so I actually think that, that the outcome of this would be to add to it you know erm comment of visitor, you know when visited, erm and it would also show the sort of regularity of visits and the difference in sort or who visits and the rest of it which might help in terms of care generally I suppose' (Family B3008)*	
Measurement properties		
Acceptability: 'ease of use' and 'value to care'	**Post-implementation**	
	'They're making a guess, that everybody in the family has had enough information as they want whether they've verbalised it or not; so they can only say have the family asked for more information and has it been provided, not that they want more' (Family B1008) *'It must be hard for staff in a care home working with people with Alzheimer's dementia to know if those residents are in any discomfort or pain, going by when [resident of B3006 – BB3003] had his fall recently, when I got to the hospital erm to see him, he had a massive*	*'I should think so because I mean we're all doing the same job, we all write care plans …' (Care home staff B3013)* *'I think mostly it's time because they are so involved in the practical needs of the residents you know, um plus a lot of them don't have very good you know handwriting [literacy] skills and that kind of thing, they weren't employed for their handwriting skills' (Manager A3001.1)* *'I think sometimes when you're talking about pain or you're talking about the way that person might be feeling you have an idea of the way they might feel but you don't really know how they are feeling because*

	Family	**Professional**
	erm swelling the side of his head and erm a big bruise, black going down towards his eye, and on the back of his head he's taken the skin off but not once, and it must have been painful, not once did he sa – did he mention that he was hurting' (Family B3006)	*they can't express themselves so …' (Care home staff B3011)* *'We are looking after the resident you see some who cannot express themselves but as a carer you notice that oh this resident, where he would try to um to behave you can see the face, the way he would do um the way he would make the face you know that oh this resident he have pain somewhere or he will hold, sometimes he will hold his stomach like that then you know oh maybe she got a pain in her stomach, maybe she constipated or maybe, so things like that they will make the sign that you, you feel that maybe she have pain' (Care home staff B3014)* *'How do you know that families get enough information relayed to them as they should have? (Care home staff B3011)* *'You know how dare you say you've given me enough information when actually you haven't spoken to me…?' (Manager B3001.2)* *'So there is a point at which the value, the value of the document comes in the document being valued' (Manager B3001.1)* *'Because they can help you to answer it, especially pains and um depression, you ask these questions and they can answer to say yes or no how I feel where with the others some of them you got to sort of you use your own skill to find out what is happening so yeah' (Care home staff A3003)* *'Well especially if they are in pain you notice you know their face expression, you notice when you're trying to do personal hygiene, if they scream, anything like that so you'll recognise that this person's in pain, um you know more sleepy, you can say they're more tired looking, more withdrawn, if it's severe or, you understand? So…'(Care home staff A3003)* *'But for in that case probably occasionally I think um probably she's a bit um anxious or having some fear that she's going to be hurt so it's sort of anticipating, thinking about that I hurt that is going to happen' (Care home staff B3012)*

	Family	**Professional**
		'I guess what I think you have to be observing more the resident as an individual more, probably within the care plans and get more information about that will help' (Care home staff B3012) *'Yeah that's the, one of the great benefits of staff being here long term, not flitting in and out because they actually know the residents and they would immediately spot any changes and know whether that was a concern or not' (Manager A3001.2)* *'So basically but then, but if you ask it like that then you've got to ask then why not and is it because I haven't seen the family, or erm I haven't had the information to give the family if I so it's 2 ways it could be no I haven't informed the family but only because I haven't seen them, or it could be no I haven't informed the family because I don't know what to inform them' (Manager B3001.1)* *'How do you know if I'm at peace?' (Care home staff B3012) … 'I don't really do I? You make an assessment you make a judgement about people but you don't really know' (Care home staff B3011)* *'This one here, can she or he enjoy activities appropriate for his or her level of interests and abilities, that's quite a hard one don't you think?' (Care home staff B3011)* *'I think it is, I think it is and I think it is, I think that is one of the questions that is open to interpretation I really do, because for some people being at peace means they're rest – they're not rest, restless, but for actually for others they could be very restless but still be at peace, because some people don't get that peace is an emotion as opposed to a s – a physical state, if, if you know where I'm going with that so it's about helping people to understand that this is about their total wellbeing, are they at, are they at erm at the point of not necessarily acceptance, but are they embracing fully where they are? Are they fighting with where they are? Are they you know are they still saying I wish, I wish, I wish, you know I wish I could do this, I wish I could do that, because if somebody says oh I wish I could walk, they actually telling*

	Family	Professional
		you they're sad that they can't and so they're not at peace because they've got that sense of not being able to do something, and I think, I think that question is going to be one that is interpreted very very differently' (Manager B3001.2)
Acceptability: comprehensiveness and relevance	**Post-implementation**	
	'...so I think you know just the over the past week where you've got I think it's question 3 to – yes it's question 3 onwards you know about their, how they are, how they're feeling, and interacting with other people and staff and I think that's really really important. Lots of people do interact and I feel my mum doesn't, and my mum's always been a party girl you know she was always get up and go,...' (Family A3002) *'Anxious, has any of her, anxious or worried about the person, I think that's important really, I mean I think, [sigh] (Family A3003)* *'but your mum's been in homes for 8 years so I wouldn't see her in the same sort of category, I wouldn't see her as having palliative care would you? (Family B3008) ... but it is really, it is the end of her life, isn't it? (Family B3007) ... yeah I suppose so (Family B3008) ... it's how long they can hang on for (Family B3010) ... I think it's also understanding that people do, as we said earlier, people do die from Alzheimer's you know it's not just a condition (Family B3007) ... oh yeah (Family B3008) ... they die from it (Family B3007)'* *'Definitely relevant because they don't even really remember, will remember themselves, I know my mum wouldn't remember any of these, she wouldn't know that she hasn't slept very well you know and I think they're, them looking out for symptoms so the night staff are they here, because they must walk round at night and if they hear some noise in the room then they know you know, not sleeping at night is you know, erm and question 3, yeah I, I think they are all relevant [pause], but as I said you know lots of things*	*'There's quite a lot, appetite, the mobility, wandering, yeah there is a lot here that would um indicate that things have changed and there's a problem' (Manager A3001.1)* *'Um no they're all quite relevant aren't they you know have the family been anxious yeah I think they are all relevant' (Manager A3001.2)*

	Family	Professional
	may go on but I'm not aware of them yeah' (Family A3002)	
Feasibility and frequency of use	**Pre-implementation**	
		'For some people it might vary, some people you might need to do it every day (Care home staff C1007) … yeah (Manager C1005) …whereas some people you might do it once a month, while some you have to do it weekly (Care home staff C1007) *'I think…if it's going to be coinciding like and implementing what's in the care plan then they all have to be done on a monthly basis and more regular if changes' (Manager C1005)* *'I mean, I suppose really the question was how often and who by and how would it help? … erm… we have a monthly assessment on their care, and I suppose really I would initially think that that is something we could use upon admission, and then monthly and then increase its usage if the level of change seemed to be more significant, or a tool that we could go back to, if we you know, we've done it and we might have done it last week, but all of a sudden we're noticing a significant change, for it to be a tool to say well come on, let's see what's going on here' (Manager B1005)*
	Post-implementation	
	'I think, I mean I think what, what is always helpful if you have to do this kind of monitoring and tracking is for it to be as simplified as possible and that it can be incorporated in the work that [care home staff] do, … it's very difficult I think these kinds of monitoring and tracking systems are just simply time consuming and sometimes do take away from the business of you know communicating and doing all the basic stuff' (Family A3004) *'Erm [pause] I think weekly, the staff would not want to do that, and possibly, they probably wouldn't want to do every 2 weeks either but I see things as 6 weeks as a teacher and you know if it was every 3 weeks or 4 weeks or every month you know that would be better than them not doing it but I can't see that happening' (Family A3002)*	*'Erm do I think you should tell people how to – how – I think if you don't give them a minimum timescale there will be those who will only use it when they know you need, they've got to, erm the thing with monthly which is, is only really coming to me as we're talking, the thing with monthly is it's only capturing one week in the month, but you can't capture a month in one tick box and I'm just thinking to be honest this would be so much easier for every staff to have one of these every Monday to fill in for the previous week or you know one day for the previous week on their key residents and then when they come to do their care plan they've got the information there' (Manager B3001.2)* *'I think you can use it like maybe for a resident that you see not having much change maybe every month or every 2 months when we're doing our care plan as well you just use that as well as part of our tool, um somebody that you see change more rapidly as the weeks go by I think it's*

	Family	Professional
		good to use more as a 2 week or you know um monthly, it just depends on how, what we notice in their behaviour and changes' (Care home staff A3003) *'Well as I said again it depends on the deterioration in some of our clients, some might deteriorate more rapidly and the ones that deteriorate more rapidly I could see I mean you could have it as a weekly but I think weekly might be a bit too much so say two weekly and the ones that is more slower erm deteriorating then that could be as our care plan because what we do we do 2 monthly for the ones that not deteriorate and as time goes as well for example if we see somebody going downhill then you use it as a weekly erm method and work with it that way so' (Care home staff A3003)* *'It depends on the person, if the person has changed before erm you, you do it next month, if the person, I'm giving an example, if the person change this week you can't wait for next month to do your book [IPOS-Dem], you have to…' (Care home staff B3014)* *'But as a, you know as a one-off, um I think it could be quite a good tool, but not to be used every week' (Manager A3001.1)* *'Possibly, maybe you know if we notice some changes in the resident we might refer back to this' (Manager A3001.1)* *'Um, intermittently, if we notice a change in a resident then we would refer back to this, perhaps go through it again and then compare how it was and how it is now' (Manager A3001.1)* *'Erm I think initially once a month or where have you is, is good, as I said earlier I think it is something that particularly if you've got somebody who's going through a change in their, their condition it could be used more frequently' (Manager B3001.1)* *'You know rather than let's rewrite the care plan every time there's a change which is the situation we're in at the moment, if somebody has a change in their condition we have to update the care plan as the condition changes so you can be writing something in the care plan every day*

	Family	Professional
		because somebody's changed whereas it would be brilliant if we would say we're noticing changes, we're going to use the [IPOS-Dem] on a weekly basis or a daily basis to monitor these changes, that would be so much easier' (Manager B3001.1) *'Not really I mean as I said if we really put our mind to it and you do one a day really it's, you know it's not that we're going to sit and do all 33 so you know if everyone really put their head to it I can see it going one a day, you know once a week somebody come in and take up this particular, especially key workers you know if one said I'll do 2 of my clients and you know I think you know it could work really' (Care home staff A3003)* *'Yeah, so yeah I mean probably in the long term I would say yes it's hard work to do 27 of these every week but nobody's doing 27, at the most they're doing 4 because they only have 4 key residents so at the most they're doing 4, so it, it's not a huge thing. Now one of the big issues of course would be the amount of paperwork you would generate. Um but I do think when you've got somebody who is changing or somebody who is unwell and you're looking to see where those changes are, it could be, it could be a useful tool to do it weekly so yeah' (Manager B3001.2)*
Validity and reliability: 'trusted assessment'	**Pre-implementation**	
	'... but to me poor appetite might be not eating for a week, for somebody else it is a different pers- they'll say poor appetite is when you haven't eaten for a couple of hours... (Family B1007) *'I'm not a fan of things like this because I don't think they're very helpful in the long run because you give them to people and they just think I've got to tick one so I'll tick this' (Family A1006)*	
	Post-implementation	
	'and they've got the time to do it honestly, truthfully, then yes because anyone that needs to look at this whether it be GP, ambulance, consultant, relative, they know exactly what is going on' (Family B3006) *'no, I think that, I mean the harm could be that it's filled in incorrectly*	*'Absolutely no consistency and I don't know if that is nationwide or whether that's just London, but London is dreadful at the moment erm and so you can train one batch of district nurses and then next lot are going to come in in a month's time and don't know what it is you're talking about so it is going to be tough, it is going to be really really tough but if it became an, a nationally recognised tool then it wouldn't matter which [Clinical Commissioning Group]*

	Family	Professional
	and then there's some sort of medical intervention which might, for instance which might not be appropriate but it seems to be as you said, a GP if they read this at all would certainly not, not act on it without err second accounting and, and getting other information from other sources before say prescribing something or whatever for depression when she's not depressed or he's not depressed or whatever' (Family B3008) *'I would say not that helpful for GPs. I'm not sure that they would tru – to be perfectly frank I don't know whether they would trust that this had been filled in correctly, whether they're talking about the same person, I don't know, I just don't feel they would use it (Family B3007)*	*you work from this would be the thing, and it also says well this is what we've been assessing so we can say to the district nurse who says you know how long's this pressure area been there? Well actually this tool was done last week and there was no pressure area last week, so before you start screaming that it's been going for months and nobody's done anything, you know' (Manager B3001.1)* *'and it's got an NHS certificate on you know it, we had exactly the same with the integrated care plan. Once they'd been trained on the integrated care plan they were happy to use it. I, I get it they're regulated as well and they're petrified of doing anything outside their regulation' (Manager B3001.1)* *'The risk is, and you're always going to have this when you've got a tick box, let's just tick a box … and that risk can only be overcome by making sure that somebody is reading the document to make sure that it's reflecting the person.' (Manager B3001.1)*
Touchscreen technology	**Post-implementation**	
	'erm I mean you know we are in the modern world, I actually think that there's no reason why each patient should not have a private folder which the family can access and so this is actually not just so that when I, I live a long way away as well and err I would like to know on a Tuesday what's happening you know I mean B1009 comes in lots so she could ask to look at the documents, she wouldn't want to access them online but you might want to access it on, you know those that use computers a lot I mean it would just be useful to, to see what's been filled in this week so you've got a, a running log of what's happening, I mean that's not a, possibly the cheapest of options as it involves all sorts of security issues and all the rest of it but I definitely think that's another way of communicating, namely that, and the staff could then say when, you know when they get a complaint about lack of, of a response they could actually say well it's on the, you know people can look it up when	*'Erm, it's a long way off but somebody's got to start planting it, and this would fit perfectly with that touchscreen situation, and if it was done in such a way that you could identify one particular aspect as well and just get the swallowing for the last 6 months or the skin integrity for the last 6 months it would be brilliant' (Manager B3001.1)* *'I mean I think it's a little while before care homes are going to be all electronic, but we're talking about a, a document with a future, not a document with a past so we have to you know think, this as it is fine, this as it is is fine but when the time comes that we've got touch screens in every communal area and what have you or tablets in our pockets, I mean I know some of the more affluent homes and have already got tablets in their pockets but you know it's just a case of I've been in to see Mrs so and so and then it can be done far more often … and if it needs to be done every day it can be done every day. If it's on a touchscreen it's not actually, you know we've been talking in terms of once a month when their care plans are done' (Manager B3001.1)*

	Family	**Professional**
	they like, it's online' (Family B3008)	*'You know because if this could go onto a tablet and you could just bring it up, pain, last 6 months, and it gives you that picture for the pain for the last 6 months that would be really good' (Manager B3001.1)*
Implementation requirements		
Leadership: Embedded into care processes	**Post-implementation**	
		'Erm for me, what I will do once the research if over you know if we continue with the document will be to say discuss it with them because we have supervision with staff every six weeks so we will ask them about their residents so if we've got this document I noticed over the last couple of months you've noticed this what have you done about it? How have you identified it?' (Manager B3001.1) *'I do think it is purely by erm people being aware that there's been changes and if this highlights it I, I don't know I think, how can I, I don't want to say big brother but somebody has to be looking at what other people are doing. There has to be a point at which staff are aware when – it's twofold really, staff have to know when they've put it down somebody's listening to it or reading it because otherwise they'll just tick anything if they're thinking oh they're not going to take any notice so there is um there is a management responsibility to make sure we follow through when the staff put the effort in to do it and I think that then will complement the staff to make sure they've done it properly because they know the management's going to look at it so it's reciprocal really ... erm if I know my boss is coming to look at something I know I'm going to do it properly because my boss is coming to look at it, if I think my boss isn't interested.' (Manager B3001.1)* *'erm, just to compare you know this with the current care plan. That's the only way you'd know if it was actually being implemented' (Manager A3001.1)* *'They just need that prompt from me have you done it, erm but again that, as I said earlier that just getting into the routine (Manager B3001.1)* *'Yeah because I'm just not used to using it, you just have to get into that mind-set of thinking it's got to be done at the end of every month' (Care home staff B3011)*

	Family	Professional
Leadership: Measure being valued	**Pre-implementation**	
		'and I know it's more work, but even if it's only a little bit, it's still more work regardless of a little or a lot but I think things like this which, I don't mean this selfishly, doesn't just look after the clients, it promotes us, it promotes the care we're giving, it promotes the way in which we work, so you know, I don't think it shouldn't be done. I think it's something that all homes should do' (Manager C1005)
	Post-implementation	
		'I think a point of, a point of reference would be explaining to staff why it's needed, you know what's led to this, why have we introduced this document. That we haven't just bought out this new document but actually that we've become aware that for, for you as a staff you have so many things to do where you have to write sentence after sentence and we're, you know we're trying to recognise that by giving you a document that basically is easier to do. I think it's about selling it from you know why, why you've done it, why you've done it in this format, and how a resident will benefit from it' (Manager B3001.1) *'I think I've been a motivator, I've had to motivate them and encourage them um I think, my role is, is to convince them a) that they're able to do it, and b) the value of doing it, um I think those are the 2 key issues really you know to say you can do this, and this is why you're doing it and I think I have to believe in it, if I don't believe in it they won't' (Manager B3001.2)*

S3 Table: Baseline IPOS-Dem question one main problems (n=32)

Main problem (included in IPOS-Dem)	**Number**
Agitation	11
Poor mobility	4
Anxious	4
Wandering	4
Pain	1
Main problem (not included in IPOS-Dem)	**Number**
Refuses care	2
Confused	2
Sleepy and withdrawn	1
Low mood, withdrawn	1
Restless about how life has turned out to be	1
Sometimes likes a lot of attention	1
Losing his voice	1
Unable to feed herself, needs prompting	1
He will over and over asking question where he is	1
Assistance at mealtimes, monitor food and fluid intake because of confusion	1
Going into the cupboard in the kitchen	1
Does not like to drink	1
Extra close supervision with daily events	1
Number of cases with no main problems	**12**
Number of cases with one main problem	**8**
Number of cases with two main problems	**5**
Number of cases with three main problems	**7**
Total number of main problems	**39**

8. Integration and discussion

8.1 Summary of main findings

This thesis reports the development and preliminary evaluation of a measure to support comprehensive assessment and management of symptoms and concerns in people with dementia living in care homes. As no comprehensive measure had been developed for use in routine care of this population, the IPOS was adapted to form IPOS-Dem. Adaptation included identifying items of less relevance and additional important symptoms and concerns to ensure that the measure was comprehensive for people living with dementia and multi-morbidities. Cognitive interviews resulted in measurement refinement and IPOS-Dem Version 3. The mechanisms of action, feasibility, acceptability and implementation requirements within the residential care home context were explored and evaluated pre-implementation and post-implementation of IPOS-Dem in routine care of recruited people with dementia. IPOS-Dem was found to have the potential to change care processes resulting in potential benefit for people with dementia and their family members. Furthermore, it was found to be acceptable and feasible for use in routine care, and implementation requirements were identified. The findings informed the development of a theoretical model that demonstrates the key mechanisms of action and potential benefit, and measurement and implementation requirements of a measure used in routine care of people with dementia in residential care homes to improve assessment and management of symptoms and concerns.

8.2 A comprehensive assessment measure of symptoms and concerns (objectives one and two)

The systematic review identified a gap of measures to support comprehensive assessment of symptoms and concerns experienced by people with dementia living in care homes. IPOS-Dem addresses this gap as a comprehensive measure developed for use by care home staff in routine care of people with dementia.

Initial scoping of the literature identified common symptoms and concerns, which were included in IPOS-Dem Version 1. The development qualitative phase allowed further exploration of symptoms and concerns that may cause distress, and allowed identification of any items of less

relevance in this population group. The result was IPOS-Dem Version 3, a comprehensive measure incorporating symptoms and concerns likely to cause distress. IPOS-Dem is therefore a measure to support systematic assessment through the identification of common symptoms and concerns in order to support management of these. There are many other measures that are used in dementia care. These include measures of quality of life, behaviours that challenge, cognition, or single symptoms. None have been developed to support comprehensive assessment of physical, emotional, social and existential symptoms and concerns experienced by older people with dementia and multi-morbidities living in care homes.

8.2.1 A measure for older people with dementia and multi-morbidities

IPOS-Dem is specifically tailored for the requirements of people with dementia with multi-morbidities living in care homes. It incorporates symptoms and concerns of dementia such as hallucinations, delusions wandering and depression. However, key throughout the development of IPOS-Dem is the knowledge that many people with dementia have multi-morbidities common in older age (34), and therefore experience symptoms and concerns beyond those of dementia. This has informed what items should be included to ensure that it is comprehensive and relevant to this population. As such, IPOS-Dem is not just a measure of dementia symptoms, but incorporates all symptoms and concerns that older people with dementia living in care homes may experience.

IPOS-Dem is developed for people with dementia throughout the disease trajectory, with the recognition that many may experience distressing symptoms and concerns related to dementia and multi-morbidities at any stage. There was some evidence from the results of the study that IPOS-Dem used in this way may support improved knowledge of the person over time, and therefore support comprehensive assessment particularly as dementia advances and towards the end of life, when there are increased challenges to assessment. Indeed, IPOS-Dem is developed with the recognition that many with dementia have challenges in expressing their wishes and concerns (40), and that proxy-completed measures are required (86). This is not to say that many people with dementia are not able to self-report symptoms and concerns, but rather to ensure that people who are not able to self-report are not excluded from assessment. IPOS-Dem manual instructs care home staff to use all available means to assess people with dementia and this includes, where possible, asking them during daily interactions.

8.2.2 IPOS-Dem: a palliative care measure to assess comprehensive symptoms and concerns

IPOS-Dem has clear overlap with quality of life, wellbeing, need and discomfort measures, yet does not measure any one of these constructs. Conceptually, IPOS-Dem assesses the aspects of quality of life, discomfort and wellbeing, and need that overlap. That is, IPOS-Dem assess aspects of quality of life that can benefit from intervention, such as physical symptoms, but not those that are beyond the remit or abilities of health and social care staff, such as characteristics of the individual or environment (74) which may be less amenable to change. Similarly, IPOS-Dem assesses those aspects of need which affect quality of life, wellbeing and discomfort but not aspects of need such as risk which may be a greater priority for professionals, but may not directly cause distress for the person with dementia. As such, IPOS-Dem fits well within palliative care as an

> 'approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual' (14)

Understanding how IPOS-Dem relates to other measures used with people with dementia in care homes is important. This understanding can inform future validation work and constructing hypotheses to test construct validity. Understanding the relationship of IPOS-Dem with other measures will also help inform further testing of IPOS-Dem as an intervention and identifying potential primary and secondary outcome measures.

8.2.3 IPOS-Dem in relation to measures of quality of life

Quality of life measures have been used in routine clinical care as complex interventions in clinical settings (75, 222), and their use in routine care is advocated to support patient-centred care. Substantial work has been undertaken in measuring quality of life in people with dementia (107-110, 223-225), and both self and proxy-reported measures of quality of life have been developed for people with dementia. In addition, a measure of social care related quality of life, with a proxy version has also been developed (226, 227). The WHO defines quality of life in older people as

> 'The product of the interplay between social, health, economic and environmental conditions which affect human and social development. It is a broad-ranging concept, incorporating a person's physical health, psychological state, level of independence, social relationships, personal beliefs and relationship to salient features in the environment. As people age, their quality of life is largely determined by their ability to access needed resources and maintain autonomy and independence' (73)

IPOS-Dem aims to assess symptoms and concerns amenable to change which care home staff, along with family members and health care professionals, may be more able to address. As such, it does not measure the construct of quality of life, which constitutes multiple factors such as individual characteristics e.g. personality/motivation or environmental characteristics e.g. social and economic supports (74), which may have variable amenity to change through the provision of health and social care. Instead, used as an intervention, IPOS-Dem may contribute to improved quality of life by improved management of symptoms and concerns. Arguably, this enhances its use as an intervention as the information obtained from completing the assessment has direct relevance to care being provided. This, in turn, makes it more likely that the measure will be more acceptable to care home staff by providing information that can inform care and therefore add value to care provision.

8.2.4 IPOS-Dem in relation to measures of wellbeing

IPOS-Dem was not developed as a measure of wellbeing, but it is helpful to examine how IPOS-Dem relates to wellbeing, and measures thereof. Different conceptual models of wellbeing exist and its relationship with quality of life is often confused (228). The terms are frequently used interchangeably (225). In dementia care, a number of wellbeing measures have been developed, all of which have a theoretical underpinning of psychological wellbeing (229-237). The most well-established measure is Dementia Care Mapping (DCM). DCM has been described as a quality of life and quality of care measure (238), although it utilises scores of wellbeing (239). DCM is underpinned by Kitwood's theory on person-centred care and was originally developed as a tool for supporting and developing person-centred care. It aimed to do so through collecting data for feedback to care teams in order to inform and improve care practice (238). Like IPOS-Dem, it is therefore both an intervention and a measure. However, IPOS-Dem aims to assess a different albeit complementary construct. Arguably, care cannot be person-centred if distressing symptoms and concerns are not addressed. IPOS-Dem fills this gap; and can potentially complement existing wellbeing measures. As wellbeing in dementia care is predominantly underpinned by psychological needs and subjective experiences (240), further work on how IPOS-Dem fits with our understanding of wellbeing in people with dementia could extend our understanding of what holistic wellbeing means for people with dementia.

8.2.5 IPOS-Dem in relation to measures of need

With the aim of assessing symptoms and concerns, IPOS-Dem could be considered a measure of need. The Oxford Dictionary defines need as

> '[To] Require (something) because it is essential or very important rather than just desirable' (241).

Maslow (1943) proposed a hierarchy of needs that apply to all humans (242). However, some groups of people, such as people with dementia living in care homes, have additional and more specific needs, (243). A useful definition of health care need is that of Stevens and Raftery as the 'ability to benefit' from health care provision (244, 245).

The Camberwell Assessment of Need for the Elderly (CANE) is one of the best known measures of need for older people with mental health problems (246) and has been validated for people with dementia living in care homes (247). CANE was based on the definition of need as a 'problem or difficulty requiring intervention or assessment' (248). There is an obvious overlap between the construct of distressing symptoms and concerns, which IPOS-Dem aims to measure, and the construct of need. However, there are some differences too. CANE, for example, assesses the domains of 'accommodation', 'looking after the home', 'food', 'self-care', 'caring for someone else', 'daytime activities', 'memory', 'eyesight/hearing/communication', 'mobility/falls', 'continence', 'physical health', 'drugs', 'psychotic symptoms', 'psychological distress', 'information', 'deliberate self-harm', 'inadvertent self-harm', 'abuse/neglect', 'behaviour', 'alcohol', 'company', 'intimate relationships', 'money/budgeting', 'benefits', 'carer's need for information', 'carer's psychological distress' (249). As such, it incorporates a broad assessment of need, both from the person's, carer's (or family's), and health care professionals' perspectives (247), and therefore includes, for example, behaviours that challenge or risk. Conversely, IPOS-Dem provides a much more detailed assessment of physical symptoms, and emotional, social and existential concerns that people with dementia in care homes may experience but does not aim to assess all domains of need. As it was not developed to assess the full construct of need, it is not defined as or called a measure of need.

8.2.6 IPOS-Dem in relation to measures of discomfort

An alternative approach taken for people in people with advanced dementia who are no longer able to communicate, is to assess discomfort (250), operationalised as the presence of

observable negative physical or emotional state (151). Discomfort measures have been developed as complex interventions for people with advanced dementia. The Serial Trial Intervention (STI), involving the assessment and treatment of discomfort in people with advanced dementia with behavioural changes has been developed and tested (40, 251). This intervention demonstrates the benefit of holistic assessment of people with dementia, and the importance of understanding potentially distressing symptoms and concerns that manifest as behavioural changes. Limitations of the intervention are that it targets only those people with dementia demonstrating behavioural changes, and so does not utilise systematic and regular comprehensive assessment of all people with dementia in care homes. Additionally, given the nature of the intervention, it requires nursing staff with a clinical qualification to assess for and treat symptoms (251). IPOS-Dem has different mechanisms of action. Instead of assessing discomfort in people who may be demonstrating signs of distress, IPOS-Dem encourages care home staff to consider whether all people with dementia may be experiencing symptoms or concerns, and use all methods of assessment. A person with dementia may not for example, not demonstrate overt signs discomfort but have poor food intake, weight loss, and on inspection of their mouth, show poor signs of oral health. IPOS-Dem prompts care home staff to consider all symptoms and concerns, and can therefore provide care home staff with an overall comprehensive 'picture of the person', which can in turn be communicated to family members and health care professionals.

8.2.7 IPOS-Dem in relation to measures of agitation

Agitation is common in dementia (33), with more than 50% of people with moderate to severe dementia in care homes experiencing agitation (252, 253). Agitation may often be a manifestation of underlying distress. Recommendations to manage agitation in dementia include comprehensive assessment to determine underlying causes including, for example, pain and physical health, depression, side effects of medication, psychosocial factors, the biography of the person including spiritual and cultural identity (254). Measures of agitation, such as the CMAI (255) are useful for quantifying the type and severity of agitation in people with dementia, however do not identify the potential underlying causes of agitation. IPOS-Dem with its aim to support comprehensive assessment of symptoms and concerns that may cause distress therefore complements assessment of agitation, and may be able to inform the assessment of underlying causes of agitation.

8.3 The mechanisms of action and potential benefit, context and implementation requirements (objectives four, five and six)

A key output of this study was a detailed understanding of how IPOS-Dem may support care processes to improve outcomes for, or potentially benefit people with dementia living in residential care homes and their family members. A detailed theoretical model was developed based on the findings. An understanding of the context and key mechanisms of action of this complex intervention were identified, including how components of the intervention may interact, what changes are expected as part of the intervention, how IPOS-Dem should be used and the degree of flexibility that can be accommodated in the use of IPOS-Dem to ensure that it is transferable to other care home settings (5). It has also allowed identification of likely outcomes. Finally, it has helped identify the structures, processes and resources required for implementation (5).This has important implications for how IPOS-Dem is further evaluated as an intervention and its implications for further training and its use in care.

8.3.1 IPOS-Dem: the interactions of context, mechanisms of action and implementation requirements

Key mechanisms of action of IPOS-Dem in routine care were identified. Importantly, an understanding of the residential care home context was gained and what is needed to support implementation. Consequently, IPOS-Dem as an intervention can now be detailed, including aspects which can be adapted to local context and those aspects which are crucial to ensure that IPOS-Dem is implemented in a way that facilitates the mechanisms of action to occur (3, 5).

IPOS-Dem prompted care home staff to think about symptoms and concerns that people with dementia might be experiencing, and therefore improved their observations and awareness. To support this IPOS-Dem needs to be done routinely and regularly so that care home staff will be regularly prompted to assess symptoms and concerns. It is important to be explicit about how often IPOS-Dem should be completed. The original IPOS-Dem manual, developed from the pre-implementation qualitative phase, advises that IPOS-Dem should be used monthly at times of care planning or at times of change in presentation. This finding was confirmed in post-implementation findings, although a few care home participants reported that IPOS-Dem could be useful on a weekly basis to ensure ongoing assessment of people with dementia. Nonetheless,

quantitative results revealed that care home staff ratings of 'time spent doing IPOS-Dem being worthwhile' decreased over the 12-weeks of implementation. This does suggest that IPOS-Dem used too frequently may be less useful and therefore less acceptable, corroborating a previous study of POS administered to people living in nursing home (157). Interestingly, in that study care home staff without a clinical qualification felt it more useful to use it weekly compared to the clinically qualified nursing staff who reported weekly was too frequent (157).

An important mechanism of action was that IPOS-Dem provided a comprehensive 'picture of the person', corroborating findings from a study examining the use of MIDOS in people with dementia in care homes (97). This was key to supporting systematic record-keeping, improved review and monitoring, facilitated communication and care planning with timely changes to care provision. IPOS-Dem needs to be done routinely and regularly to ensure these mechanisms of action occur. At a minimum, IPOS-Dem should be done at times of care planning to ensure that it informs care plans and supports changes to care provision, and it should also be completed at times of change.

Care home staff participants discussed the usefulness of using IPOS-Dem at times of change or deterioration. However, there was little data regarding what change would prompt IPOS-Dem to be completed. Care home staff appeared to demonstrate an implicit understanding of when a person with a dementia may be deteriorating or unstable, but did not articulate how they may present or be identified. Understanding this is important to ensure that people with dementia who are unstable or deteriorating are correctly identified. In palliative care clinical settings, a Phase of Illness measure has been used to identify and classify patients as stable, unstable, deteriorating, dying and deceased (256). Such a measure which is brief and easy to use may support identification of people with dementia who may be unstable, deteriorating or dying in care homes; and support care planning and referrals to additional services if required (85). A limitation, however, is that it has not been validated or tested in people with dementia living in care homes by care home staff without a clinical qualification.

This study identified significant challenges to communication between family members and care home staff. Both groups of participants identified challenges but expressed different perspectives and causes. Family members identified a role of supporting assessment, advocating, engaging and accessing care, corroborating findings from previous studies (48, 50, 257-259). IPOS-Dem

was perceived as supporting family involvement in assessment. The current IPOS-Dem manual states that care home staff should speak to family members to inform their assessment. However, the actual process of this occurring was less clear. Implicit in this process, was that care home staff would complete IPOS-Dem independently of family members, then utilise IPOS-Dem to communicate their assessments to family members. Both family members and care home staff perceived IPOS-Dem as a means of opening a dialogue about the assessment, providing the opportunity to discuss any areas of disagreement thus further informing assessment. It may not be practical or feasible for care home staff to speak to family members before each IPOS-Dem assessment is completed. Doing so may delay its completion, or result in IPOS-Dem not being completed at times of care plans. However, what is essential is that family members have the opportunity to read, comment and discuss IPOS-Dem assessments with care home staff, and agree any changes to care plans or action plans as a result; either through formal or informal discussions with family members. Given the identified challenges of communication between care home staff and family members and that family members may feel excluded from and disempowered in the caring role (48), this is a potentially important and novel intervention to support integrated working between care home staff and family members.

Pre-implementation findings revealed that there were some challenges to communication between care home staff due to shift work and care home staff being on leave. This led to the IPOS-Dem manual stating that care home staff should consult other care home staff particularly those working different shifts, and read case notes to inform their assessment. The manual also states that care home staff should report symptoms and concerns to senior care home staff. These processes occurred during implementation of IPOS-Dem and post-implementation data revealed a much more detailed understanding of the process of communication between care home staff. In particular, care home staff reported how IPOS-Dem could be integrated into formal care processes, including supervision and to ensure that IPOS-Dem assessments are read on return from leave. This has implications for future IPOS-Dem training and the requirement for IPOS-Dem to be integrated into formal care processes to support this mechanism of action.

IPOS-Dem intervention was identified as facilitating communication between care home staff and health care professionals. However, the qualitative interviews and focus groups, and non-participant observations data were less revealing about how this should occur with challenges

being identified to these processes. Participants reported that IPOS-Dem would be useful to communicate symptoms and concerns to GPs, DNs, and other health care professionals. However, concerns were raised that GPs would not have the time to read all IPOS-Dem assessments. Participants also identified that DNs may not acknowledge IPOS-Dem assessments unless it was recognised and accepted as an NHS assessment, and ratified by their organisation, and the importance of IPOS-Dem being 'trusted' as an assessment was therefore identified. This has important development and training implications for IPOS-Dem. Not only is it essential that psychometric properties are tested, but it is also important that care home staff, family members and health care professionals are aware of these properties so that IPOS-Dem is recognised as a 'trusted' assessment. This is likely to present a challenge to the future implementation of IPOS-Dem. While it may be possible to implement IPOS-Dem into residential care homes, a greater implementation challenge will be facilitating external health care professionals to accept and utilise IPOS-Dem assessments. Options to address this may include developing resources for health care professionals such as brief leaflets to provide information on the validity and reliability of IPOS-Dem and how it can support care provision to benefit people with dementia.

There is no standard model of how health care services are provided to care homes, with a great deal of variation depending on how local services and working relationships have evolved (63, 66). Indeed, each of the three participating care homes had different ways of working with GP providers. As such, it is not possible to be prescriptive about how IPOS-Dem is used to work with health care professionals. A previous study using POS found that nursing home staff found it useful to share POS scores and assessments with GPs during consultations (157). The current IPOS-Dem manual states that IPOS-Dem can be used to support communication between care home staff and health care professionals. It also advises care home staff of the importance of ensuring identified symptoms are treated, and that this may be urgent if a score is severe or overwhelming. However, it may not possible to dictate to care homes and health care providers how this is best done, and local arrangements will need to be agreed.

The original theoretical model developed for this study hypothesised that scores on IPOS-Dem would support prioritisation of treatments and interventions, and support communication between all. Family and care home staff participants shared how scores could alert them to symptoms and

concerns that needed acting upon, with some participants sharing how monitoring of scores over time could be useful, with change in scores being a useful prompt to action. There was little data on how participants may interpret scores, or how they would prioritise based on scoring. There was also little data on how participants may use scores to support communication. A key property of measures used in routine care is interpretability, detailed in Section 1.3.4, meaning that scores should be clinically interpretable (11). It is unclear whether the lack of data about scores relates to care home staff having no difficulty interpreting scores, whether participants paid little attention to scores, or whether over time as IPOS-Dem became more integrated into care processes, scores would be integrated into use and language of IPOS-Dem. The findings from the study examining implementation of POS in a nursing home and hospice found that participants wanted access to analysed data which was not easily available and beyond the resources of the sites. However, this appeared to be more of a barrier for the hospice setting who wanted the data to predict outcomes, while the nursing home site appeared to find access to summary scores sufficient (157). It may be that for use in routine care, the participants found no requirements for analysed IPOS-Dem data but if these data were identified for further use, then care home staff may wish to have access to resources to analyse and interpret data. Senior care home staff did identify the benefit of having scores for individual people with dementia over time, and the usefulness of receiving feedback of aggregate scores over time as a quality indicator of how well the care home is responding to symptoms and concerns addressed.

Technology that can analyse individual scores as well as aggregate scores, and that can be easily used with the resources of care homes are likely to enhance acceptability and support implementation (157). Touchscreen technology was identified as facilitating completion of IPOS-Dem, providing alerts of symptoms and concerns to prompt changes to care, overcome storage challenges, and support monitoring and communication. Family members would welcome online access to completed IPOS-Dem.

The potential benefit of using IPOS-Dem for people with dementia and their family members were identified as improved symptom management, improved care of comprehensive emotional, social and existential concerns, and increased family empowerment and engagement in care. This study's original theoretical model anticipated outcomes of reduced unmet need, improved quality of life and improved satisfaction with care. However, there was no data on whether addressing

symptoms and concerns these may improve quality of life, wellbeing, reduce discomfort, reduce unmet need, or improve satisfaction with care in people with dementia or their family members; all of which might be anticipated. There is limited evidence on the effectiveness of measures used in routine care on quality of life and symptom burden outcomes (7). Another possible expected outcome of improved symptom and management and improved care of comprehensive concerns is reduced agitation, with evidence that improved pain management reduces agitation in people with advanced dementia (41). However, this was not identified as a potential outcome in this study either.

Risks of using IPOS-Dem and implementation requirements mitigating risks

None of the participants identified any risks of using IPOS-Dem to people with dementia. However, there were identified risks of mechanisms of action not occurring. These included risks of inaccurate assessment, risks of symptoms and concerns being identified but not acted upon, and risks of barriers in accessing health care due to health care professionals not accepting care home staff completed IPOS-Dem assessments.

The IPOS-Dem manual was developed to minimise some of these risks with information on how IPOS-Dem may support care, instructions on how to assess people with dementia utilising all available information, what to do if symptoms and concerns are identified, and how IPOS-Dem can be used to support communication. The care homes were provided with copies of IPOS-Dem and the instruction manual. As the video version manual was not ready by the time this phase of the study started, this was not available to provide to care home staff. There was very little evidence of the care home staff reading or using the manual before starting to use it in care. This may be in part due to the fact that the majority of participants found reading and comprehending the manual challenging. However, Slade et al (1999) suggests that most health care professionals will start using a measure in routine care before reading the manual (13). Despite this, care home staff appeared to have a good understanding of how to assess symptoms and there was good evidence that symptoms and concerns were escalated to senior care home staff or managers. Care home participants appeared to intuitively understand how IPOS-Dem could support care, and how it should be best used to support care. Indeed, data collected from care home staff extended the understanding of how IPOS-Dem could support care processes. This corroborates earlier studies of comprehensive measures used in routine care of nursing home residents which

demonstrated that care home staff understood the benefit of using a measure in routine care (97, 157). There was little evidence in this study of managers or senior care home staff taking on a role of providing this information, although they did identify that resources for care home staff including how IPOS-Dem can support care, would support their implementation of IPOS-Dem.

All participants identified how IPOS-Dem could support communication. Participants reported that this in turn could improve collaborative assessment with family members, and access to health care external from the care home. However, such a measure cannot change culture of care, and cannot change care home relationships with family members and health care professionals. In this study, participants demonstrated the desire to work together for the benefit of people with dementia. However, there was also evidence of some of the challenges of working with health care professionals. Participants also noted the requirement for a transparent and honest working relationship. An intervention such as IPOS-Dem cannot change working relationships, but may through shared documentation provide a shared language to support integrated working (260). A realist review of interventions to improve health care for people in care homes identified the requirements of care home staff being engaged from the outset and the intervention supporting the priorities and structures of the care home (260) in order to achieve expected outcomes. This study takes this a step further by developing an intervention which is (i) led by care home staff and implemented into routine care by care home staff, (ii) utilises care home staff skills and expertise in caring for people with dementia and their knowledge of residents, and (iii) is integrated into care home processes and structures by care home staff in order to facilitate integrated working between care home staff and health care professionals. This is important as interventions for care homes should ideally be developed in collaboration with care home staff, family members and where possible residents, to ensure an understanding of the care home context and that the intervention is tailored to context (176).

Leadership was essential to support implementation, supporting existing evidence of implementing measures into routine care (261). Managers and senior care home staff identified their role in integrating IPOS-Dem into routine care processes, indicating the requirement for managers to have the motivation and understanding of the benefit of using IPOS-Dem in routine care. If this is done well, such as IPOS-Dem being incorporated into supervision, handover meetings, and processes are developed for working with family members and health care

professionals, many of the risks will be mitigated. As one manager expressed, it is important that IPOS-Dem assessments are seen by managers and other care home staff, and that if care home staff believe that nobody will review their IPOS-Dem assessments, then they will not put sufficient effort into ensuring that it is accurate (Chapter 7, supplementary table 2 – Implementation requirements). This finding is similar to a previous one which demonstrated POS integrated into weekly team meetings at a nursing home by senior care home staff meant that care home staff could see the relevance of using POS to care (157). Another senior care home staff member expressed how despite the fact that she was using IPOS-Dem, recognised the benefit of all care home staff using it, and the benefit of integrating it into routine care processes, she felt that she was unable to do implement these changes without the support of the manager.

Many health care interventions designed and developed for care homes require 'high facilitation' by health care professionals to be implemented and sustained (262, 263). Indeed, the realist review identified the importance for visiting health care professionals to provide ongoing support to care home staff to support how interventions were implemented and delivered (260). Another study, examining the implementation of a comprehensive admission assessment into hospice setting discussed the importance of interactional workshops, feedback sessions and opportunities for critical reflection to successfully change practice (264). This study found that care home staff identified how to integrate IPOS-Dem into routine care, recognised benefit to care processes, and used IPOS-Dem without external facilitation. This demonstrates IPOS-Dem may not require a high degree of external facilitation for its implementation into routine care. This is important for the implementation of IPOS-Dem to be accessible, scalable and feasible for implementation. However, it is important to take into consideration that the participating care homes agreed to participate in the research and were therefore likely more amenable to implementing a new intervention. The care home staff had also contributed to the development of IPOS-Dem and were therefore more invested in using and evaluating it. In addition, while I had not been involved in prompting or facilitating the use of IPOS-Dem in routine care, it is likely that my working relationship that developed over the course of the study may have influenced care home staff's engagement in the use and implementation of IPOS-Dem. There is, therefore, a potential risk that without external facilitation, IPOS-Dem may not be implemented, or that symptoms and concerns may be assessed but not addressed. Working with an external facilitator, such as a palliative care team may support care home staff in their integration of IPOS-Dem into routine care, support

them in accurate assessment of people with dementia, and identify means of addressing symptoms and concerns. This, in turn, would support collaborative and integrated working.

8.4 Acceptability and feasibility of IPOS-Dem (Objectives three, four and seven)

IPOS-Dem was found acceptable and feasible for use in routine care of people with dementia. Key to its acceptability was that participants recognised the value that it could provide to care. Participants identified a number of ways in which IPOS-Dem supported care and therefore its acceptability was enhanced. For this reason, the measurement properties of acceptability and feasibility were included in the theoretical model as they essential if the mechanisms of action are to occur, and for the measure to be successfully implemented (261).

A central mechanism of action was the comprehensive 'picture of the person' that IPOS-Dem provided. Participants valued that IPOS-Dem assessed physical symptoms and emotional, social and existential concerns; and that this information was portrayed in concise and succinct format thus supporting care planning, record-keeping, monitoring of people with dementia, and communication. This was a finding of MIDOS being used in nursing home residents. In that study care home staff valued the comprehensive nature of MIDOS and also reported that it supported the same mechanisms of action (97). Participants also reported that IPOS-Dem was relevant to the care that is being provided, with no items being identified that were not important to people with dementia. These findings demonstrate the value of rigorous and significant developmental work of IPOS-Dem to ensure that it is a comprehensive and relevant measure; and that important symptoms and concerns were identified but items of less relevance were not retained. It also demonstrates how using an appropriate measure which has been developed for the purpose is important. A quality of life or needs assessment measure may not have been sufficiently relevant to be acceptable to care home staff. However, a measure to support a palliative care approach of comprehensive assessment and management of symptoms and concerns to reduce distressing symptoms and concerns, is one that family members and care home staff recognise as providing value to care. These findings also demonstrate the strength of adapting an existing measure that is established as a measure for use in routine clinical care (87), providing the

opportunity to build upon the substantial research and development that has already been conducted internationally (85, 143, 158).

IPOS-Dem is developed for care home staff without a clinical qualification, and it was important that this was taken into consideration as part of its development to ensure its ease of use. Cognitive interviewing proved essential in this process to ensure that the language used was comprehensible and acceptable to care home staff, and qualitative and quantitative results demonstrated that IPOS-Dem is easy to use. Nonetheless, there remain challenges to assessing people with dementia, particularly in those who have challenges verbally expressing their wishes and concerns. Care home staff are not able to rely on clinical examination to assess people with dementia and both in the development and evaluation of IPOS-Dem, there was data that demonstrated assessment challenges, particularly in people with more complex symptom presentation. Care home staff also expressed concerns and uncertainty about the accuracy of their assessment, corroborating findings from the study of MIDOS in people with advanced dementia (97); and missing data was for the most part attributable to the option 'cannot assess' being selected. This uncertainty could, however be a strength. It is certainly preferable that care home staff question and scrutinise their own assessments rather than confidently assume that their assessments are accurate. It is also reflected in the care home staff's expression of how using IPOS-Dem 'makes you think' about symptoms and concerns that residents may be experiencing. However, it also does indicate that there are further training requirements to support care home staff in their assessment of people who may have challenges expressing the wishes and concerns. Many measures developed to assess symptoms and concerns in people with dementia are based on observations. There are therefore observable symptom indicators that people may have when experiencing a symptom. The systematic review (chapter two) identified that significant research has been conducted into the assessment of pain in people with dementia, but that further research is needed into care home staff assessment of other symptoms and concerns.

IPOS-Dem was also found to be feasible. Flexibility of use supported feasibility, with care home staff expressing the benefit of using it regularly but also using their own judgement if IPOS-Dem needs to be used more frequently. Leadership integrating IPOS-Dem into routine processes will also enhance feasibility. Individual care homes would therefore benefit of deciding how frequently

IPOS-Dem is used so that they are best integrated into care processes, with a minimum of IPOS-Dem being used at times of care planning. It should be noted that it is likely that IPOS-Dem may be less acceptable if used too frequently as it may become burdensome and cease to provide valuable information in people with dementia who are stable.

8.5 Strengths, challenges and limitations

8.5.1 Recruitment, retention and attrition of residential care homes

A strength of the study was that strong working relationships were developed and maintained with the care homes and that the work was seen as important by care home staff as a means to improve care for people with dementia. Maintaining a working relationship centred on the enthusiasm and commitment of the care home staff. Working with care home staff on the conduct of the study (265), understanding the priorities of the care homes, flexible working including evening and weekend working, and time and patience were also essential. Frequently, planned sessions had to be cancelled at the last minute due to an incident occurring at the care home or problems with staffing. Recognising the work priorities and challenges that care home staff faced, consulting them, and utilising their expertise was essential in maintaining good working relationships throughout (195). I believe that my own clinical background greatly assisted this, meaning that I had a good understanding of clinical and care priorities that care home staff face. However, there were challenges to conducting this study.

An early challenge was identifying suitable residential care home sites. The limited resources and time constraints of the PhD meant that only one local authority was selected. This was to limit the number of Local Authority Governance approvals, and respective NHS site approvals for GP and DN participation required. This is a limitation as the care homes recruited were from the same area in London limiting the diversity of the population.

A strength of the study was that recruitment of care homes was relatively successful. Only one care home approached declined participation stating that the home was undergoing managerial changes and the future of the care home was uncertain. Once permissions had been obtained from the care home providers to approach the care home staff directly. Managers and care home staff demonstrated interest and enthusiasm at participating in the study. This recruitment rate of

care homes for this study is much higher than has been reported in literature with care home recruitment rates ranging from 27% to 73%, and researchers generally being required to approach 40% more care homes than they require (195). However, a consequence of recruiting from one local authority was that the number of eligible residential care homes was limited. This was further limited by recruiting residential care homes with a mix of funding types and ownership.

Another challenge was the retention of care homes associated with changes in senior care home staff. Between the development and evaluation phases, the manager of Care Home C left and as a consequence there were many staff changes. Although good working relationships had been developed with the care home, there was evidently much uncertainty and low morale within the care home. It was therefore decided to suspend the care home's participation in the study until the new manager had started. Once the new manager had commenced, I approached the manager on a few occasions but was unable to make contact; and eventually a decision had to be taken to not pursue this as any further delays would result in significant delays to the study. At the same time, the option of recruiting a fourth residential care home was considered, one whose manager had previously expressed interest in participating. However, this option was not progressed due to the requirement to get care home site approval from the ethics committee, and the consequent delays to the study. This resulted in the limitation that only two residential care homes participated in the final phase of the study, with the loss of a larger care home run by an organisation. Retaining this care home in the final phase of this study would have further enhanced the evaluation of IPOS-Dem by providing data of it being used in a third and different setting, and an increased sample size of people with dementia receiving the intervention.

8.5.2 Recruitment and attrition of people with dementia

This study rigorously adhered to ethical procedures and protocols in recruiting people who lack capacity (266). There are substantial challenges to recruiting people who lack capacity, and these were identified prior to the study commencing (197). As such, a detailed recruitment protocol was developed drawing upon previous research of recruiting adults lacking capacity (198) and living in care homes (197, 267). This included the methods of identifying eligible people with dementia, assessing capacity, gaining informed consent for adults with capacity or using a process of assent for adults lacking capacity, identification of a personal consultees, using nominated consultees when no personal consultee was available, and developing study information sheets accessible

to people with dementia and their family members (169, 173, 197, 198, 267, 268). Despite this, there were some foreseeable but unavoidable complications which had a negative impact on the number of people with dementia recruited to the study. The main reason was the loss of Care Home C to the study which was registered to care for people with dementia and had 29 beds.

Of the 47 identified eligible participants in Care Homes A and B, 36 (76.6%) were recruited. This is relatively high in comparison to previous studies which when adhering to the same rigorous ethical standards have achieved recruitment rates of 42% (269) and 62.1% (197). Successful recruitment was facilitated by the support of CRN SL Division 4 DeNDRoN in providing a nominated consultee who was both knowledgeable about the research but independent from the research study.

Another unavoidable challenge to retention of resident participants was attrition due to death. Given the study's population of older people with cognitive impairment and multi-morbidities, this was expected and demonstrates that the study had recruited the relevant population under question to the study (159). Nonetheless the number of deaths was higher than anticipated based on previous studies of people with dementia in care homes (41). In total, eight out of the eligible 47 (17.0%) died. Three eligible resident participants died before being recruited, four out of the recruited 36 (11.1%) died before baseline data collection. Two more participants were lost during the course of the study due to death (n=1) and moving to a nursing home (n=1). As a consequence, the sample size of 32 at baseline and 30 at final time point is small, and limited the analysis that could be conducted and the conclusions that can be drawn from the analysis.

A consequence of the high number of deaths which almost entirely occurred in one care home was the effect that this had on care home staff. It was clearly a challenging time for care home staff who lost an unprecedented number of people who they care for a short space of time. This needed to be handled sensitively, taking into account care home staff's feelings, and giving them time to process their feelings.

8.5.3 Recruitment of family members

There were challenges to recruiting family members. A barrier was that family members could not be approached directly. This project therefore utilised methods used in previous studies, including

posters to advertise the study and coffee mornings in each of the participating care homes (197, 268). These were held during the weekends to facilitate family members' attendance. Study materials were made available to family members, and they were given the opportunity to ask questions, and if they or the person with dementia wished, the opportunity to decline participation. Despite these processes, it was still difficult to recruit family members. The majority of family members attending the coffee morning were interested in participating, but attendance at the coffee mornings was limited. The evaluation phase had slightly better recruitment. This was mostly due to those family members who had acted as personal consultees, expressing interest in participating in their own right. Focus groups were conducted at care homes and during weekends at a time convenient for the majority participants, and interviews were conducted at the preferred time and location of participants to optimise recruitment. Nonetheless, while family members expressed interest and willingness to participate, the biggest challenge was their availability particularly as the evaluation phase data collection was shortly before Christmas. Despite this, data saturation was achieved; and no new themes were being generated from conducting further interviews.

8.5.4 Recruitment of care home staff

To facilitate engagement with care home staff, I met with the staff to discuss the study and consult with them regarding the process of conducting the study. The study was generally met with support and care home staff expressed interest in participating. Care home staff were purposively sampled to gain a range of seniority and care roles. Nonetheless, a limitation was the availability of willing care home staff due to shift work and care priorities in the care home, and dependency on managers or senior care home staff to release care home staff from their duties. To overcome some of these barriers and support care home staff attending, light meals and refreshments were provided to care home staff participants.

Fewer care home staff participated in the evaluation phase. This was in the most part due to attrition of Care Home C. Another reason was the limited implementation in Care Home A. One senior staff member used IPOS-Dem in care of people with dementia, discussed the benefits of using it and of all care home staff using it, but felt unable to implement it across the care home due to the lack of the manager's support.

8.5.5 Recruitment of health care professionals

Before the study commenced, it was identified that health care professionals may be a challenging participants to recruit to due clinical priorities. This proved to be the case. In the development phase, recruitment of GPs was reasonably successful. However, between the two phases, the GP working with Care Home A changed, and despite repeated attempts to contact the GP and practice manager, the new GP did not respond to approaches to participate in the study. In the evaluation phase, the GP working with Care Home B remained engaged in the study and interested in participating but clinical priorities resulted in an inability to participate in a focus groups or an interview. This GP did, however, participate in non-participant observations.

Recruitment of DNs proved particularly challenging. Strategies utilised to recruit DNs involved meeting with the community nursing manager to discuss the study. With the support and agreement of the community nursing manager, the study was presented to all DNs in the borough in one of their meetings. Individual DNs working with participating care homes were then approached to participate. Using this approach was reasonably successful in the development phase with DNs from all three care homes expressing interest in participating, although one was unable to attend the focus group due to work commitments. However, between the two phases, there was a change in the community nursing manager, and it proved difficult to engage this manager in the research. Without the leadership support and approval, it was impossible to recruit DNs resulting in no DNs participating in the evaluation phase.

8.5.6 Challenges, strengths and limitations of multiple methods of data collection

A strength of this study was that it utilised multiple types of qualitative and quantitative data collection as a means of evaluating IPOS-Dem. This enhanced the understanding of its use in routine care, allowed for data to be triangulated and strengthened the overall findings. However, there were challenges to multiple types of data collection. In particular, for a novice researcher, there was much learning required in the different methods of data collection and data analysis.

A challenge of the study was the planned analysis of the case note data extraction. Case note data extraction was resource intense. Data entry of these data was also extremely resource intense. It was a limitation of the study that the quality of the case note was generally poor. Health care professional consultations, care plans, medications, and medical histories were poorly

documented. This is likely a reflection of that this is not a clinical setting, that care home staff have limited access to medical records, and that they do not hold a clinical qualification. However, it did mean that the case note data extraction was of limited value in evaluating IPOS-Dem, and the time and resources required into detailed analysis of the records was not warranted. Only baseline demographic and clinical data were utilised for the purpose of the study. This has ethical implications; as approval had been obtained to gain access to case notes, and resources had been used to extract these data. It is therefore important that the collection of these data is not wasted. As such, further analysis is planned but is not utilised for the purposes of this study.

Another challenging aspect of data collection was non-participant observations. Using this method of data collection was a strength of the study, as it enhanced the understanding of how health care professionals worked with care home staff. A limitation is that only one health care professional could be recruited to non-participant observation, thus limiting the understanding of how health care professionals work with care homes to one GP who had good working relationships with the care home. The data from non-participant observations was also limited in providing insights into how IPOS-Dem may support integrated working between care home staff and health care professionals. Successful recruitment of health care professionals in the evaluation phase to participate in interviews or focus groups would have greatly enhanced the understanding of the this mechanism of action.

8.5.7 Reflexivity and positionality

I am an occupational therapist and have worked extensively with care homes in a clinical capacity. I was therefore aware that I was entering this field with a set of assumptions from my clinical experiences. These assumptions were about care home settings, the care provided, and about the care home staff, family members, and health care professionals. As a novice researcher, I had another set up of assumptions, partly informed by my clinical experiences, my knowledge of the literature and discussions with more senior colleagues.

The requirement for me to deliver the PhD, meant that I worked hard to develop strong working relationships with potential participants. In particular, with care home managers and care home staff; and also with health care professionals and family members. This involved meetings, informal discussions, and emails. I quickly realised that I was learning much about the care home

context, relationships, and that the recordings in my reflective diary were in fact a source of data. I had not gained ethical approval to analyse my own observations and reflections, and I was therefore not able to use the diary as a source of data. Nonetheless, the diary proved invaluable in both my own learning, skill development, understanding of the care home context and dynamics and relationships between participant groups. In addition, I was able to reflect in my diary on my own role and relationships with participants, and how this may have affected data collection and data analysis. The following is an extract from my diary from the first focus group of the study, and indeed the first ever study data collection I had conducted:

> *I was very pleased at the eventual participation in the focus group. Two GPs participated and a care home DN attended. In the end, two care home staff also participated. While I was really pleased that this number of healthcare staff attended (which exceeded [my] expectations) it did create an imbalance in the focus group. This was further exacerbated by the fact that the two care home staff who did participate were very junior and not involved in the assessment of residents.*
>
> *On reflection I think that the power balance was wrong with the GPs being very vocal and the care home staff may have felt intimidated. Also, healthcare staff definitely had their own priorities and care home priorities were not really considered. I think that I could have better facilitated this and probed the care home staff more when they did contribute…*
>
> *I think that my key learning is that was too deferential. I am not suggesting that I should not have been this as I think it is really important to show that you respect the participants input. I could, however, questioned their input more and tried to get rationale for their suggestions….*
>
> *My biggest criticism of my moderating is that I really did not allow or facilitate the care home staff's participation. I think that I should have probed much more and really encouraged their participation. Again, I think my own anxiety means that I was being too deferential to the GPs at the cost of the care home staff. (PhD reflective diary, 13/05/2014)*

This reflection helped me recognise and consider the nature of working relationships and provided me with an insight of the care home context. The reflection also helped me consider my own role, my relationships with participants and the impact that this was having on the data collection. While I did not use the diary entries as study data, they facilitated my data analysis to be both more insightful and reflexive. This entry enabled to recognise some of the limitations to the data that I had collected, but also gave me deeper understanding of the relationships and the context that I was studying, which informed my data analysis. The diary also enabled my learning of the research processes, and through this learning, I was consciously able to improve my facilitation, including use of probing, ensuring quieter participants had the opportunity to contribute, and developing confidence to question participants more deeply.

8.5.8 The study in relation to methods of measurement development, and the MRC guidance and MORECare statement

A strength of this study, was that it was informed and underpinned by the MRC guidance (2, 93) and MORECare statement (159) and drew upon the more recent MRC process evaluation guidance (3) with the aim of understanding the mechanisms of action, acceptability, feasibility and implementation requirements of IPOS-Dem. The study was also informed by the methods of developing a measure (10) to ensure that rigorous methods in measurement development were employed. This meant there were challenges at times in combining the two approaches.

Informed by the MRC guidance and MORECare statement, IPOS-Dem was developed as a complex intervention underpinned by a theoretical model. This proved essential in the development of IPOS-Dem as an intervention. As a consequence, a conceptual model of the construct that IPOS-Dem has been developed to measure was not developed, a potential limitation. However, the development of IPOS-Dem including the pre-clinical (Chapter 5) and the development phase qualitative focus groups and interviews (Chapter 6, publication 2) had the clear objectives of developing IPOS-Dem to measure symptoms and concerns experienced by people with dementia in care homes. Cognitive interviewing recommended in the development of measures were also utilised (Chapter 6, publication 2). IPOS-Dem therefore does have established content validity. With the focus on IPOS-Dem as an intervention, another limitation was that it was beyond the remit of this study to conduct a full psychometric evaluation of IPOS-Dem, including testing its validity, reliability, responsiveness, and interpretability.

The original MRC guidance proposes a linear approach to developing and evaluating interventions. More recent MRC guidance publications advise that the process may not be linear or even cyclical (2), with the importance of process evaluations being emphasised (3). In keeping with the newer MRC guidance, this study has not adhered rigidly to the linear approach. The development phase of this study aimed to develop IPOS-Dem with regards to its content validity, feasibility and acceptability, and also gain a pre-implementation understanding of the likely mechanisms of action and implementation requirements in the care home context so as to develop an instruction manual. The evaluation aimed to evaluate IPOS-Dem in routine care, to further understand the likely mechanisms of action, acceptability, feasibility and implementation requirements. Data collection for these study phases were conducted separately in two phases.

For clarity and to aid more detailed understanding and comparison of the pre-implementation and post-implementation findings, the study findings are published and presented according to the study objectives; and not by study phase. While this is a strength of the study, the study could be criticised as not following a clearly 'step-by-step' approach.

The MRC guidance and MORECare statement recommend that both the feasibility of the intervention and feasibility of methods for full scale evaluation of the intervention are evaluated in the feasibility study. Testing the methods of a full scale cluster-randomised trial, was beyond the remit of this study. Nonetheless, the findings of this study provides valuable insights into some of the challenges of such research, and which methods will require testing in a feasibility study.

This study aimed to conduct a feasibility and process evaluation in order to understand how IPOS-Dem works in the care home context, and the requirements of implementation. The MRC process evaluation guidance details key components of process evaluations. These include context, implementation and mechanisms of action (3). As this study was designed and was underway prior to the publication of the MRC process evaluation guidance, the guidance did not inform or underpin the study design. However, a strength of this study is that it aimed to examine in detail the residential care home context and how the mechanisms of action worked within this context. The implementation requirements of IPOS-Dem were also examined although implementation was not examined to the full extent recommended by the MRC guidance on process evaluations (3). At this stage of IPOS-Dem development and evaluation, the study aimed to understand what would be required to support implementation. The findings of this study informed and therefore allowed IPOS-Dem as an intervention to be detailed. This included which aspects were essential in order for the mechanisms of action to occur, which aspects can adapted to local context, the 'dose' of IPOS-Dem or frequently it should be used, and how it should be integrated into routine care to support the mechanisms of action to occur. It was therefore too early in its development and evaluation, to evaluate fidelity, dose, adaptations and reach. However, as a result of this study these can now be defined and tested against pre-defined criteria of IPOS-Dem as an intervention.

8.5.9 IPOS-Dem and its resources

IPOS-Dem: what's in a name?

The name of IPOS-Dem changed through the course of the study, reflecting the rationale and thinking that occurred during the process of development. At the start of the study, and to reflect that IPOS-Dem was developed from the original and validated POS, the measure was called POS-Dem. During the course of the study and in response to feedback and potential criticism that POS-Dem was being developed as an intervention, and that no psychometric evaluation was being undertaken as part of the PhD, the name was changed to POS-Dem Assessment. This was to reflect the nature of POS-Dem Assessment as an assessment and not as an outcome measure. In the final stages of its development, in consultation with and at the request of the international POS development group, the name was changed to IPOS-Dem. This change was made to reflect that IPOS-Dem is a version of IPOS, and most closely aligned with IPOS in the POS family of measures.

IPOS-Dem resources: guidance to support assessment of symptoms and concerns in people who have challenges expressing their wishes and concerns

Accurate assessment of people who have difficulties in verbally expressing their wishes and concerns is challenging. Recognising this challenge, the systematic review was conducted to identify measures that had been developed to assess people with compromised verbal communication utilising symptom indicators. The original aim of the study was to develop IPOS-Dem with symptom indicators (signs or behaviours indicating that a person may experience a symptom) to support assessment in people with dementia. However, it became evident that to achieve this with the methodological rigour required, would require substantial work beyond the resources and time permitted by the PhD. PhD supervision was important at this time to recognise the limits of what could be achieved with the available time and resources; and identify that this could be a development area for future research. It is therefore an unsurprising finding that care home staff found assessment of some people with dementia challenging, and that missing data was mostly due to the challenges of assessment in this population. The findings of the study are informative to identify areas that were particularly challenging for care home staff to assess including pain, nausea, constipation, sleeping problems, and hallucinations and delusions. In addition, the systematic review identified that it is challenging for care home staff to accurately detect depression in this population group. This is an important area for future development.

IPOS-Dem resources: manual and video manual

An important strength of this study was the in-depth understanding gained of how IPOS-Dem may support care in the residential care home context, and how it may be integrated into existing care processes in order to support implementation. To support care home staff understanding of this, and therefore support its implementation, a manual was developed (Appendix O). The findings from cognitive interviews demonstrated that care home staff had difficulties in reading comprehension of IPOS-Dem manual, and despite substantial effort to simplify language, a written manual was not a sufficient resource to support care home understanding of the purpose of IPOS-Dem and how it should be used to improve care. A prototype video version of the manual was developed, but it was not ready for testing by the time IPOS-Dem was implemented into routine care of residents. Further advancements in IPOS-Dem, in particular, the name change, rendered the video out of date quite quickly. This demonstrates the challenges of keeping resources current with ongoing developments. To optimise the resources available, the production of the video manual was not progressed. This was to allow for further understanding and awareness of potential training requirements of IPOS-Dem so that these could be incorporated into future video manuals and training.

8.6 Research implications

8.6.1 IPOS-Dem: defining the intervention

IPOS-Dem can now be clearly detailed as an intervention to improve assessment and management of symptoms and concerns experienced by people with dementia and their family members. This includes how it should be integrated into care processes, how frequently it should be used, and aspects of IPOS-Dem that can be adapted to local context.

Essential components of IPOS-Dem are detailed as follows:

(i) IPOS-Dem is completed by care home staff at baseline (on admission) of all people with dementia, and then at times of care planning, usually monthly. An option is that IPOS-Dem can be used in routine care more frequently, but it is recommended that it is not used more frequently than weekly for people who are stable, as it is likely that IPOS-Dem would not provide further helpful information, become increasingly burdensome and lose its value. IPOS-Dem is used by care home staff more frequently at their own judgement, if they notice a change in presentation of the person with dementia.

(ii) At a minimum, completed IPOS-Dem assessments should be made available to family members; and family members should be provided with the opportunity to comment and make changes to IPOS-Dem assessments. How this is done, will necessarily be according to individual care home processes. It is also recognised that not all family members may wish to engage in this process, but family members should be offered this opportunity. As an option, care home staff may choose to complete IPOS-Dem in consultation with family members.

(iii) IPOS-Dem should be incorporated into care home staff supervision. This ensures that care home staff know that the assessments will be reviewed and seen by senior care home staff. Discussing IPOS-Dem assessments in supervision can facilitate monitoring of the accuracy of assessments by senior care home staff; and can support care planning by identifying any symptoms and concerns that need acting upon, and how best to address these.

(iv) Symptoms and concerns rated three or four should be immediately escalated to senior care home staff. Senior care home staff should monitor in supervision whether they are being alerted to significant symptoms or concerns.

(v) Care homes may consider the option of incorporating IPOS-Dem discussions into handover or any meetings. This will depend on existing processes of care homes and how IPOS-Dem may be best integrated into these.

(vi) IPOS-Dem may be used to communicate symptoms and concerns to health care professionals. How this is done will depend on the working relationships care home staff have with health care professionals. It is likely that GPs will not have time to review IPOS-Dem for all patients that they are reviewing. However, IPOS-Dem may be useful for patients with more complex presentation to inform GPs of symptoms and concerns, and thus inform GPs' assessments. IPOS-Dem may also be used with other health care providers such as mental health teams and specialist palliative care to communicate care home staff assessment.

8.6.2 Psychometric evaluation of IPOS-Dem

Chapter one identified important measurement properties that are required for measures to be used in routine care. This study has evaluated the acceptability, comprehension, and feasibility of IPOS-Dem. Further testing is required to establish its validity, reliability, interpretability and

responsiveness. These requirements were evident from the findings of this study. Establishing the psychometric properties of IPOS-Dem will facilitate its implementation through increasing its recognition as a 'trusted' measure, important if health care professionals are to recognise the IPOS-Dem assessments conducted by care home staff, and act upon the identified symptoms and concerns.

Psychometric evaluation is challenging in proxy-completed measures; when there is an absence of a gold-standard to assess criterion validity. Psychometric evaluation should include assessment of construct validity through hypothesis testing of relationships, and strengths of relationships with other valid measures (106, 270), such as agitation; and through testing of structural validity through factor analysis. Reliability testing should include testing of internal consistency, test-retest reliability in groups of stable people with dementia, and inter-rater reliability (270). It is proposed that inter-rater reliability is assessed through evaluation of IPOS-Dem completed by care home staff and specialist palliative care health care professionals to determine how care home staff assess in comparison to assessment by expert health care professionals. Responsiveness will be tested through longitudinal construct validity (270). Finally, given the potential usefulness of using IPOS-Dem in settings beyond residential care homes and its potential usefulness in supporting communication across health and social care sectors, psychometric testing across care settings (including, for example, nursing homes and inpatient wards) is warranted. This will extend accessibility of IPOS-Dem.

8.6.3 IPOS-Dem intervention: identified areas for further developments

Further areas of IPOS-Dem development have been identified from this study, which would support the implementation and use of IPOS-Dem into routine care:

(i) Development of training resources and materials to support assessment in people who have challenges in expressing their wishes and concerns. Further research will need to be conducted as to what materials may best support assessment. One option is to utilise 'bolt-on' validated measures that are already established to support assessment of symptoms such as PAINAD for pain. However, this will have an impact on the feasibility of using IPOS-Dem. Another option is to synthesise symptom indicators from the measures with the strongest psychometric properties to develop training resources and materials to support care home staff assess symptoms and concerns.

(ii) IPOS-Dem manual: the video manual can now be further developed with guidance on how IPOS-Dem should be integrated into routine care, detailing the essential and optional components. IPOS-Dem training should also detail how IPOS-Dem may support care processes and provide value to care, by improving assessment and management of symptoms and concerns.

(iii) As one of the findings of this study was the challenge of health care professionals recognising IPOS-Dem as a measure. Further development is required to determine what resources may support health care professionals to recognise and utilise IPOS-Dem in routine care. Further information materials and resources may be warranted for health care professionals, or a dissemination strategy to health care professionals developed.

(iv) Previous POS developments have included a decision-support tool to facilitate and support health care professionals in managing identified symptoms and concerns, based on evidence-based interventions (105). To further develop IPOS-Dem as an intervention to improve person-centred care, it is proposed that a decision-support tool be developed. Such a tool will include established evidence-based person-centred interventions, and alert care home staff to referring to health care professionals when required. The decision-support tool will be based on scoring thus further supporting interpretability of scores (11, 105).

(v) Finally, development of an electronic format of IPOS-Dem that can be used with touchscreen technology is warranted. This will increase IPOS-Dem acceptability and facilitate mechanisms of action of IPOS-Dem being used in routine care.

8.6.4 Feasibility trial and full IPOS-Dem evaluation

IPOS-Dem as an intervention needs testing to ascertain its effectiveness at improving outcomes for people with dementia and their family members through a cluster-randomised trial. An identified limitation of this study was that the methods for a full scale evaluation were not tested. A mixed-methods feasibility cluster-randomised trial will provide the opportunity to identify primary and secondary outcome measures, calculate the required sample size, and test methods for health economic evaluation (2, 93). A feasibility trial will also allow further process evaluation of IPOS-Dem including fidelity, reach, dose and implementation of training resources (3).

8.6.5 Ethical implications for future research with people with dementia living in care homes

A substantial amount of work was involved in applying the ethical and legal guidelines of conducting research in adults lacking capacity. The study drew upon the MCA (173), guidelines (169) and previous research (197-199). Identifying and contacting personal consultees proved challenging with only 15/44 (35.1%) of eligible residents having next-of-kin who were contactable and who responded stating they were prepared to act as consultees. Having an identified nominated consultee was essential in recruitment of people with dementia. This highlights the importance of identifying a nominated consultee who has dedicated time to speak to residents, care home staff and family members or friends, and read case notes in order to advise on participating in research. It is also essential that the nominated consultee has a good understanding about what participating in the research entails as well as the role of consultee in research.

It was anticipated that those residents that had capacity to consent, may lose capacity over the course of the study. The MORECare statement on ethical issues in palliative and EoLC research (169) recommends that in conducting research in people who lack capacity or may lose capacity over the research study, consent is gained from the person and advice obtained from the consultee. In this way, the MCA (173), can be adhered to, if participants lose capacity. This approach is also less invasive as the participant is approached only once to assess capacity and gain informed consent, rather than at each data collection point. Only one participant was assessed as having capacity and this participant preferred to meet with me with his next-of-kin and personal consultee. As such the study was discussed with them both, and they had the opportunity to discuss potential participation between them. The method therefore seemed to work well for them both. However, taking this approach may have presented challenges if they had disagreed about participation. It is less certain what the most ethical course of action may have been under these circumstances. Future studies considering this approach, should have clear plans about what steps should be taken under these circumstances.

8.7 Implications for care

IPOS-Dem is developed for care home staff assessment and management of symptoms and concerns for people with dementia living in residential care homes, addressing an identified gap. As such it has generated clinical interest, with a number of requests and enquiries having been received regarding its implementation into care. This presents a challenge and a dilemma. IPOS-Dem requires further testing. On the other hand, judging by the interest that IPOS-Dem has generated, there evidently appears to be an important need; and withholding IPOS-Dem while further testing is conducted will mean there will continue to be unaddressed care need for a substantial period of time. A decision was therefore taken to make IPOS-Dem publicly and freely available for use in care and IPOS-Dem with its instruction manual is now available on the POS website (154).

IPOS-Dem has generated interest beyond residential care homes; and it has now been implemented in clinical care by specialist palliative care teams in residential and nursing homes, hospices and community settings for people with dementia. A Clinical Commissioning Group is conducting a six-month audit of a pilot implementation of IPOS-Dem in nursing homes, residential care homes, an acute hospital ward, mental health ward, and community settings with the plan of extending to all commissioned sites by the end of the audit period. A mental health trust is currently considering its use for patients with dementia and a national dementia charity has expressed plans to implement IPOS-Dem in a number of services that it funds both to support care and as a service evaluation.

This interest has resulted in opportunities to further understand IPOS-Dem in routine care. Collaborations have been developed and data sharing agreements have been agreed and signed between organisations so that IPOS-Dem data generated in routine care can be analysed, in conjunction with demographic and clinical data (such as medical conditions), as well as measures of phase of illness (256), FAST (32), Australia-modified Karnofsky Performance Status (271). This is of benefit to both parties as analysed data can be shared with clinical/care teams; and further IPOS-Dem data can be accessed. This will inform understanding of IPOS-Dem acceptability and feasibility, and potential benefit through data on numbers of measures completed, missing scores, scores over time, and IPOS-Dem in relation to demographic and clinical data. It is anticipated that

these data, in conjunction with the results of this study will support future funding applications for further development and testing of IPOS-Dem.

8.8 Next steps

At the time of writing, a grant application to Dunhill Medical Trust had been submitted to secure funding for developing IPOS-Dem training resources, and further psychometric evaluation of IPOS-Dem. This has gone through to the final stage and a full application has therefore been submitted. This is a priority given IPOS-Dem is already being implemented into routine care of people with dementia. Translation and psychometric evaluation has commenced in Germany and due to be commenced in Switzerland, with groups from the Netherlands and Sweden also having expressed interest in translating IPOS-Dem.

8.9 Personal reflections and learning

This PhD was my first research job. Prior to commencing it I had worked clinically. I am passionate about interventions to improve the lives of people with dementia and knew that this was the research topic for my PhD. Improving the lives of people with dementia in care homes seemed to me a particularly important topic. In preparing my PhD question, I read much about the challenges of conducting research with care homes and with people with dementia who lack capacity. I believed that this, along with my understanding of the care home environment from my clinical experience prepared me well for conducting the research. I quickly learnt of the real-life challenges of conducting research despite my careful preparation. I learnt of the importance of developing and maintaining good strong working relationships, and ensuring that the care needs of the residents and supporting the care home staff to meet these needs, had to be prioritised over my study. I therefore learnt that it is important to make compromises and that it is essential to be flexible. In the earlier stages of the PhD, I saw every compromise as a failure on my part to deliver a high-quality research, and struggled with the uncertainty of further challenges. Through supervision and as I progressed and developed, I was to learn that all research has limitations and that it is important to recognise and acknowledge these, and how they may affect the study results and interpretation of results. Nonetheless, this newly acquired knowledge has helped me in planning future research. When I recently prepared a grant application, this understanding was

essential in helping me think about the time and funding required to support such research, and I was able to write the grant application taking these considerations into account.

8.10 Contribution to the science of developing and evaluating measures for clinical/care use

PCOMs or measures used in routine care has been recognised as a means of improving person-centred care for people with advancing illness or palliative care needs (7, 84, 272). However, the majority of evidence for their use is with patients with cancer (75, 222). There is little evidence of their use in care homes, in people with dementia who may not be able to verbally communicate their wishes and concerns, or in populations with multi-morbidities (7). This is important as with an ageing population, there is likely to be a growing population of people who may have complex symptoms and concerns as a result of dementia and/or multi-morbidities (27, 34) and who may require care in a care home (55). Assessing and addressing their symptoms and concerns is an essential part of providing person-centred care, and PCOMs provide a means of doing so (7). However, we need to understand how such measures may work best for this population and this setting, and ensure that they are developed to take into account the population and setting requirements.

This thesis contributes to the science of developing and evaluating measures in clinical/care use in the following ways:

(i) Essential to this was adapting an existing measure rather than developing a new measure. Choosing a measure that had been developed for clinical use and that was already well-established meant that I could build upon existing evidence and science. It was also important not to add to the multiple measures used in advanced illness (84, 121), but rather contribute and build upon an existing one thus extending its use for this population and setting. The approach of having a core palliative care measure with additional symptom and setting items combines the requirement for standardisation with the flexibility for use across population settings (272). The result of this study is a proxy-reported measure developed for use in routine care of people with dementia living in residential care homes to support systematic assessment and management of symptoms and concerns.

(ii) The study identifies the measurement properties required for use in routine care and ensures that these are taken into consideration from the outset of development. This ensures that the measure is developed to be acceptable and feasible for use in routine care. Essential to this was the involvement in care home staff who would be using it. Care home staff were consulted on its development and how it should be used to support routine care during the development phase of the study (272). Involving family members proved essential in ensuring that the requirements of them and residents were incorporated.

(iii) This study focuses on identifying the key mechanisms of action of using a measure in routine care. It therefore extends our understanding of how measures may work, particularly proxy-reported measures for people with dementia in care homes. This study supported and builds upon previous findings that measures used in routine care may improve comprehensive detection of symptoms, facilitate communication and lead to changes in care provision (7). However, this study provided a more in-depth understanding of how a measure may support communication, and particularly multi-agency working through provision of a comprehensive and complex assessment in a succinct and easily accessible format. This is important and potentially has implications beyond the residential care home setting to all people with complex and multiple care needs cared for multiple agencies, and their family members. This study also identified that such measures may support regular review, monitoring, and systematic record-keeping, and by doing so, may support provision of end of life care. Again, this has implications beyond the population of dementia living in residential care homes to populations with chronic or progressive diseases.

8.11 Conclusion

IPOS-Dem is a measure developed for care home staff assessment and management of symptoms and concerns of people with dementia in residential care homes and their family members, addressing an important gap. It has been developed to support comprehensive assessment, incorporating important and relevant symptoms and concerns experienced by people living with dementia and multi-morbidities and their family members. In addition, it has been developed with an understanding of the care home context, and an understanding of care

home staff knowledge, skills and remit in providing care for people with dementia. IPOS-Dem used in routine care may change care processes including improved observation and awareness of symptoms and concerns, and improved collaborative assessment; thus providing a 'picture of the person'. This 'picture of the person' in turn supports systematic record-keeping, monitoring, care planning and multi-agency communication. It therefore addresses important challenges in the care of this population by supporting comprehensive assessment of people with dementia, and supporting integrating working between care home staff, family members and health care professionals. The potential benefit of IPOS-Dem includes improved symptom management, improved care of emotional, social and existential concerns, and increased family empowerment and engagement in care. IPOS-Dem was found to be acceptable and feasible for use in routine care, with findings that it is easy to use and provides value to care. The implementation requirements of IPOS-Dem have been identified, particularly the importance leadership in enabling care home staff to recognise the value of using IPOS-Dem and ensuring it is integrated into care processes. Important areas for further research are the psychometric evaluation of IPOS-Dem in care homes and across care settings, and testing of the research methods for a full trial on the effectiveness of IPOS-Dem to improve outcomes of care for people with dementia living in care homes.

9. References

1. Care Quality Commission. Care Quality Commission: Care homes; 2016. Available from: http://www.cqc.org.uk/content/care-homes. Accessed 5 August 2016.
2. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337(sep29_1):a1655-a.
3. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350.
4. Power R, Langhaug LF, Nyamurera T, Wilson D, Bassett MT, Cowan FM. Developing complex interventions for rigorous evaluation--a case study from rural Zimbabwe. Health Education Research. 2004;19(5):570-5.
5. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance. Available from: https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/. Accessed 29 March 2017.
6. Donabedian A. The quality of care. The Journal of the American Medical Association. 1988;260(12):1743-8.
7. Etkind SN, Daveson BA, Kwok W, Witt J, Bausewein C, Higginson IJ, et al. Capture, Transfer, and Feedback of Patient-Centered Outcomes Data in Palliative Care Populations: Does It Make a Difference? A Systematic Review. J Pain Symptom Manage. 2015;49:611-24.
8. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. British Medical Journal. 2010;340:c186.
9. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. Journal of Clinical Epidemiology. 2010;63(7):737-45.
10. de Vet HC, Terwee CB, Mokkink LB, Knol DL. Measurement in medicine. Cambridge: Cambridge University Press; 2011.
11. Higginson IJ, Carr AJ. Using quality of life measures in the clinical setting. British Medical Journal. 2001;322:1297-300.

12. Bausewein C, Simon ST, Benalia H, Downing J, Mwangi-Powell FN, Daveson BA, et al. Implementing patient reported outcome measures (PROMs) in palliative care–users' cry for help. Health and Quality of Life Outcomes. 2011;9(27):1-11.
13. Slade M, Thornicroft G, Glover G. The feasibility of routine outcome measures in mental health. Social Psychiatry and Psychiatric Epidemiology. 1999;34(5):243-9.
14. World Health Organization. World Health Organization definition of palliative care 2017. Available from: http://www.who.int/cancer/palliative/definition/en/. Accessed 25 May 2017.
15. World Health Organization and Alzheimer's Disease International. Dementia: a public health priority. Geneva, Switzerland: World Health Organization; 2012.
16. Alzheimer's Disease International. The global voice on dementia; 2014. Available from: http://www.alz.co.uk/. Accessed 7 June 2017.
17. Mitchell SL, Black BS, Ersek M, Hanson LC, Miller SC, Sachs GA, et al. Advanced dementia: state of the art and priorities for the next decade. Annals of Internal Medicine. 2012;156:45-51.
18. Mitchell SL, Kiely DK, Hamel MB. Dying with advanced dementia in the nursing home. Archives of Internal Medicine. 2004;164(3):321-6.
19. World Health Organization. Dementia Fact Sheet: World Health Organization; 2017. Available from: http://www.who.int/mediacentre/factsheets/fs362/en/. Accessed 1 August 2017.
20. Department of Health. Living well with dementia: a national dementia strategy. Crown Copyright; 2009.
21. Department of Health. End of life care strategy. Crown Copyright; 2008.
22. van der Steen JT, Radbruch L, Hertogh CM, de Boer ME, Hughes JC, Larkin P, et al. White paper defining optimal palliative care in older people with dementia: A Delphi study and recommendations from the European Association for Palliative Care. Palliative Medicine. 2014;28(3):197-209.
23. Alzheimer's Disease International. World Alzheimer Report 2015: the global impact of dementia. London: Alzheimer's Disease International; 2015.
24. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. The Lancet. 2012;380(9836):37-43.

25. Todd S, Barr S, Roberts M, Passmore AP. Survival in dementia and predictors of mortality: a review. International journal of geriatric psychiatry. 2013;28(11):1109-24.
26. Office for National Statistics. Deaths registered in England and Wales (Series DR): 2015: Office for National Statistics; 2016. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredinenglandandwalesseriesdr/2015. Accessed 29 May 2017.
27. Etkind SN, Bone AE, Gomes B, Lovell N, Evans CJ, Higginson IJ, et al. How many people will need palliative care in 2040? Past trends, future projections and implications for services. BMC Med. 2017;15(1):102.
28. World Health Organization. International statistical classification of diseases and related health problems 10th Revision. 2010.
29. Stephan B, Brayne C. Prevalence and projections of dementia. In: Downs M, Bowers B, editors. Excellence in dementia care: research into practice. New York: Open University Press; 2008.
30. Molloy DW, Alemayehu E, Roberts R. Reliability of a standardized mini-mental state examination compared with the traditional mini-mental state examination. The American Journal of Psychiatry. 1991;148(1):102-5.
31. Reisberg B, Ferris SH, de Leon MJ, Crook T. The Global Deterioration Scale for assessment of primary degenerative dementia. The American Journal of Psychiatry. 1982;139(9):1136-9.
32. Reisberg B. Functional assessment staging (FAST). Psychopharmacology Bulletin. 1988;24(4):653.
33. Lyketsos CG, Lopez O, Jones B, Fitzpatrick AL, Breitner J, DeKosky S. Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment: Results from the cardiovascular health study. Journal of the American Medical Association. 2002;288(12):1475-83.
34. Public Health England. Dying with Dementia: National Dementia Intelligence Network and National End of Life Care Intelligence Network Briefing. Crown Copyright; 2016.
35. Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K. Frailty in elderly people. The Lancet. 2013;381(9868):752-62.
36. Johnell K. Inappropriate Drug Use in People with Cognitive Impairment and Dementia: A Systematic Review. Current Clinical Pharmacology. 2015;10(3):178-84.

37. Parsons C. Polypharmacy and inappropriate medication use in patients with dementia: an underresearched problem. Therapeutic Advances in Drug Safety. 2017;8(1):31-46.
38. National Institute for Health and Clinical Excellence. Multimorbidity: clinical assessment and management; 2016. Available from: https://www.nice.org.uk/guidance/ng56/chapter/Recommendations. Accessed 15 May 2017.
39. Corbett A, Husebo B, Malcangio M, Staniland A, Cohen-Mansfield J, Aarsland D, et al. Assessment and treatment of pain in people with dementia. Nature Reviews Neurology. 2012;8(5):264-74.
40. Kovach CR, Cashin JR, Sauer L. Deconstruction of a complex tailored intervention to assess and treat discomfort of people with advanced dementia. Journal of Advanced Nursing. 2006;55(6):678-88.
41. Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. British Medical Journal. 2011;343:d4065.
42. Lyketsos CG, Carrillo MC, Ryan JM, Khachaturian AS, Trzepacz P, Amatniek J, et al. Neuropsychiatric symptoms in Alzheimer's disease. Alzheimer's & dementia : the journal of the Alzheimer's Association. 2011;7(5):532-9.
43. Knapp M, Chua K-C, Broadbent M, Chang C-K, Fernandez J-L, Milea D, et al. Predictors of care home and hospital admissions and their costs for older people with Alzheimer's disease: findings from a large London case register. BMJ Open. 2016;6(11).
44. Luppa M, Luck T, Weyerer S, König H-H, Brähler E, Riedel-Heller SG. Prediction of institutionalization in the elderly. A systematic review. Age and Ageing. 2010;39(1):31-8.
45. Yaffe K, Fox P, Newcomer R, Sands L, Lindquist K, Dane K, et al. Patient and caregiver characteristics and nursing home placement in patients with dementia. Journal of the American Medical Association. 2002;287(16):2090-7.
46. Hébert R, Dubois M-F, Wolfson C, Chambers L, Cohen C. Factors Associated With Long-term Institutionalization of Older People With Dementia Data From the Canadian Study of Health and Aging. The Journals of Gerontology: Series A. 2001;56(11):M693-M9.
47. Knapp M, Prince M, Albanese E, Banerjee S, Dhanasiri S, Fernandez JL, et al. Dementia UK: The full report. London: Alzheimer's Society; 2007.

48. Moyle W, Edwards H, Clinton M. Living with loss: dementia and the family caregiver. Australian Journal of Advanced Nursing. 2002;19(3):25-31.
49. Hennings J, Froggatt K. The experiences of family caregivers of people with advanced dementia living in nursing homes, with a specific focus on spouses: A narrative literature review. Dementia. 2016.
50. Davies S, Nolan M. 'Making it better': Self-perceived roles of family caregivers of older people living in care homes: A qualitative study. International Journal of Nursing Studies. 2006;43(3):281-91.
51. Lievesley N, Crosby G, Bowman C. The changing role of care homes. London: Bupa and Centre for Policy on Ageing; 2011.
52. Van den Block L, Smets T, van Dop N, Adang E, Andreasen P, Collingridge Moore D, et al. Comparing Palliative Care in Care Homes Across Europe (PACE): Protocol of a Cross-sectional Study of Deceased Residents in 6 EU Countries. Journal of the American Medical Directors Association. 2016;17(6):566.e1-.e7.
53. Care Quality Commission. The state of adult social care services 2014-2017. Newcastle upon Tyne: Care Quality Commission; 2017.
54. National Audit Office. The adult social care workforce in England. London: National Audit Office; 2018.
55. Bone AE, Gomes B, Etkind SN, Verne J, Murtagh FEM, Evans CJ, et al. What is the impact of population ageing on the future provision of end-of-life care? Population-based projections of place of death. Palliative Medicine. 2018; 32(2): 329-36.
56. Skills for Care. Care homes without nursing in the adult social care sector 2016/2017. Leeds: Skills for Care; 2017.
57. Skills for Care. The state of the adult social care workforce in England. Leeds: Skills for Care; 2017.
58. Gov.UK. What qualification levels mean: Crown Copyright; 2018. Available from: https://www.gov.uk/what-different-qualification-levels-mean/list-of-qualification-levels. Accessed 6 April 2018.
59. Skills for Health. The Care Certificate 2018. Available from: http://www.skillsforhealth.org.uk/standards/item/216-the-care-certificate. Accessed: 6 April 2018.

60. Goodman C, Robb N, Drennan V, Woolley R. Partnership working by default: district nurses and care home staff providing care for older people. Health & Social Care in the Community. 2005;13(6):553-62.
61. Luff R, Ferreira Z, Meyer J. Care homes. London: NIHR School for Social Care Research; 2011.
62. Owen T, Meyer J, Bentley J, Heath H, Goodman C. Better partnership between care homes and the NHS: Findings from the My Home Life programme. Journal of Care Services Management. 2008;3(1):96-106.
63. Davies S, Goodman C, Bunn F, Victor C, Dickinson A, Iliffe S, et al. A systematic review of integrated working between care homes and health care services. BMC Health Services Research. 2011;11(1):320.
64. Gage H, Dickinson A, Victor C, Williams P, Cheynel J, Davies SL, et al. Integrated working between residential care homes and primary care: a survey of care homes in England. BMC Geriatrics. 2012;12(1):71.
65. Goodman C, Woolley R, Knight D. District nurses' experiences of providing care in residential care home settings. Journal of Clinical Nursing. 2003;12(1):67-76.
66. Iliffe S, Davies SL, Gordon AL, Schneider J, Dening T, Bowman C, et al. Provision of NHS generalist and specialist services to care homes in England: review of surveys. Primary Health Care Research & Development. 2016; 17(2): 122-137.
67. British Geriatrics Society. Quest for quality: A joint working party inquiry into the quality of healthcare support for older people in care homes. London: British Geriatrics Society; 2011.
68. Hancock GA, Woods B, Challis D, Orrell M. The needs of older people with dementia in residential care. International Journal of Geriatric Psychiatry. 2006;21(1):43-9.
69. Glendinning C, Jacobs S, Alborz A, Hann M. A survey of access to medical services in nursing and residential homes in England. British Journal of General Practice. 2002;52(480):545-8.
70. Mann AH, Schneider J, Mozley CG, Levin E, Blizard R, Netten A, et al. Depression and the response of residential homes to physical health needs. International Journal of Geriatric Psychiatry. 2000;15(12):1105-12.
71. Moriarty J, Rutter D, Ross PDS, Holmes P. End of life for people with dementia living in care homes. London: Social Care Institute for Excellence; 2012.

72. Gillick MR. Adapting advance medical planning for the nursing home. Journal of Palliative Medicine. 2004;7(2):357-61.

73. World Health Organization. Ageing and health technical report Volume 5 Geneva: World Health Organization Centre for Health Development; 2004. Available from: http://www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf. Accessed 3 July 2017.

74. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. Journal of the American Medical Association. 1995;273(1):59-65.

75. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM, et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. Journal of Clinical Oncology. 2004;22(4):714-24.

76. Hill N. Use of quality-of-life scores in care planning in a hospice setting: a comparative study. International Journal of Palliative Nursing. 2002;8(11):540-7.

77. Quill TE, Abernethy AP. Generalist plus Specialist Palliative Care — Creating a More Sustainable Model. The New England Journal of Medicine. 2013;368(13):1173-5.

78. Hendrix CC, Sakauye KM, Karabatsos G, Daigle D. The use of the Minimum Data Set to identify depression in the elderly. Journal of the American Medical Directors Association. 2003;4(6):308-12.

79. van der Steen JT, Goodman C. What research we no longer need in neurodegenerative disease at the end of life: the case of research in dementia. Palliative Medicine. 2015;29(3):189-92.

80. Hall S, Kolliakou A, Petkova H, Froggatt K, Higginson IJ. Interventions for improving palliative care for older people living in nursing care homes (review). Cochrane database of systematic reviews. 2011(3):CD007132. doi:10.1002/14651858.CD007132.pub2.

81. Murphy E, Froggatt K, Connolly S, O'Shea E, Sampson EL, Casey D, et al. Palliative care interventions in advanced dementia. Cochrane database of systematic reviews (Online). 2016;12: CD011513. doi:10.1002/14651858.CD011513.pub2.

82. Higginson IJ, Carr AJ. The clinical utility of quality of life measures. In: Carr AJ, Higginson IJ, Robinson PG, editors. Quality of life. London: BMJ Books; 2003.

83. Department of Health. Equity and Excellence: Liberating the NHS. London: The Stationery Office; 2010.

84. Harding R, Simon ST, Benalia H, Downing J, Daveson BA, Higginson IJ, et al. The PRISMA Symposium 1: Outcome Tool Use. Disharmony in European Outcomes Research for

Palliative and Advanced Disease Care: Too Many Tools in Practice. Journal of Pain and Symptom Management. 2011;42(4):493-500.

85. Witt J, Murtagh FE, de Wolf-Linder S, Higginson IJ, Daveson BA. Introducing the Outcome Assessment and Complexity Collaborative (OACC) suite of measures. London: King's College London; 2014.
86. Smith S, Lamping D, Banerjee S, Harwood R, Foley B, Smith P, et al. Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology. Health Technology Assessment. 2005;9(10):1-93, iii-iv.
87. Hearn J, Higginson I. Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. Quality in Health Care. 1999;8(4):219-27.
88. McPherson CJ, Addington-Hall JM. Judging the quality of care at the end of life: can proxies provide reliable information? Social Science & Medicine. 2003;56(1):95-109.
89. Lichtner V, Dowding D, Esterhuizen P, Closs S, Long A, Corbett A, et al. Pain assessment for people with dementia: a systematic review of systematic reviews of pain assessment tools. BMC Geriatrics. 2014;14(1):138.
90. Weiss CH. Nothing as practical as a good theory: exploring theory-based evaluation for comprehensive community inititiatives for children and families. In: Connell JP, Kubisch AC, Schorr LB, Weiss CH, editors. New Approaches to Evaluating Community Initiatives Volume 1 Concepts, Methods and Contexts. Washing D.C.: The Aspen Institute; 1995.
91. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C, et al. Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials. 2014;15:267.
92. Mason P, Barnes M. Constructing Theories of Change: Methods and Sources. Evaluation. 2007;13(2):151-70.
93. Medical Research Council. A framework for development and evaluation of RCTs for complex interventions to improve health, 2000. Available from: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372. Accessed 29 March 2017.

94. Gilissen J, Pivodic L, Gastmans C, Van der Stichele R, Deliens L, Breuer E, et al. How to achieve the desired outcomes of advance care planning in nursing homes: a theory of change. BMC Geriatrics. 2018;18(1):47.
95. Blamey A, Mackenzie M. Theories of change and realistic evaluation peas in a pod or apples and oranges? Evaluation. 2007;13(4):439-55.
96. Fuchs-Lacelle S, Hadjistavropoulos T, Lix L. Pain assessment as intervention: a study of older adults with severe dementia. The Clinical Journal of Pain. 2008;24(8):697-707.
97. Krumm N, Larkin P, Connolly M, Rode P, Elsner F. Improving dementia care in nursing homes: Experiences with a palliative care symptom-assessment tool (MIDOS). International Journal of Palliative Nursing. 2014;20(4):187-92.
98. Evans BC, Coon DW, Ume E. Use of Theoretical Frameworks as a Pragmatic Guide for Mixed Methods Studies. Journal of Mixed Methods Research. 2011;5(4):276-92.
99. Tashakkori A, Creswell JW. Exploring the nature of research questions in mixed methods research. Journal of Mixed Methods Research. 2007;1(3):207-11.
100. Slade M. Routine outcome assessment in mental health services. Psychological Medicine. 2002;32(08):1339-43.
101. Worldwide Palliative Care Alliance. Global atlas of palliative care at the end of life. London: Worldwide Palliative Care Alliance; 2014.
102. Greenhalgh J, Long AF, Flynn R. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? Social Science & Medicine. 2005;60(4):833-43.
103. Aveyard B, Davies S. Moving forward together: evaluation of an action group involving staff and relatives within a nursing home for older people with dementia. International Journal of Older People Nursing. 2006;1(2):95-104.
104. van Soest-Poortvliet MC, van der Steen JT, Zimmerman S, Cohen LW, Reed D, Achterberg WP, et al. Selecting the Best Instruments to Measure Quality of End-of-Life Care and Quality of Dying in Long Term Care. Journal of the American Medical Directors Association. 2012;14(3):179-86.
105. van Vliet LM, Harding R, Bausewein C, Payne S, Higginson IJ. How should we manage information needs, family anxiety, depression, and breathlessness for those affected by advanced disease: development of a Clinical Decision Support Tool using a Delphi design. BMC Medicine. 2015;13(1):1-20.

106. Terwee CB, Bot SD, de Boer MR, van der Windt DlA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. Journal of Clinical Epidemiology. 2007;60(1):34-42.
107. Ettema T, Droes R, de Lange J, Mellenbergh G, Ribbe M. A review of quality of life instruments used in dementia. Quality of Life Research. 2005;14(3):675 - 86.
108. Moyle W, Murfield JE. Health-related quality of life in older people with severe dementia: challenges for measurement and management. Expert Review of Pharmacoeconomics & Outcomes Research. 2013;13(1):109-22.
109. Perales J, Cosco T, Stephan B, Haro J, Brayne C. Health-related quality-of-life instruments for Alzheimer's disease and mixed dementia. International Psychogeriatrics. 2013;25(5):691 - 706.
110. Ready RE, Ott BR. Quality of life measures for dementia. Health and Quality of Life Outcomes. 2003;1(11).
111. Mahoney RI, Barthel DW. Functional Evaluation: the Barthel Index (BI). Maryland State Medical Journal. 1965(14):56-61.
112. Bucks RS, Ashworth DL, Wilcock GK, Siegfried K. Assessment of activities of daily living in dementia: development of the Bristol Activities of Daily Living Scale. Age and Ageing. 1996;25(2):113-20.
113. Voigt-Radloff S, Leonhart R, Schutzwohl M, Jurjanz L, Reuster T, Gerner A, et al. Interview for Deterioration in Daily Living Activities in Dementia: construct and concurrent validity in patients with mild to moderate dementia. International Psychogeriatrics. 2012;24(3):382-90.
114. Teri L, Truax P, Logsdon R, Uomoto J, Zarit S, Vitaliano PP. Assessment of behavioral problems in dementia: the revised memory and behavior problems checklist. Psychology and Aging. 1992;7(4):622-31.
115. Allen RS, Burgio LD, Roth DL, Ragsdale R, Gerstle J, Bourgeois MS, et al. The Revised Memory and Behavior Problems Checklist-Nursing Home: Instrument Development and Measurement of Burden Among Certified Nursing Assistants. Psychology and Aging. 2003;18(4):886-95.
116. Iverson GL, Hopp GA, DeWolfe K, Solomons K. Measuring change in psychiatric symptoms using the Neuropsychiatric Inventory: Nursing Home version. International Journal of Geriatric Psychiatry. 2002;17(5):438-43.

117. Cummings JL. The Neuropsychiatric Inventory Assessing psychopathology in dementia patients. Neurology. 1997;48(5 Suppl 6):10S-6S.
118. Reisberg B, Auer SR, Monteiro IM. Behavioral Pathology in Alzheimer's Disease (BEHAVE-AD) rating scale. International Psychogeriatrics. 1996;8:301-8.
119. Rosen J, Burgio L, Kollar M, Cain M, Allison M, Fogleman M, et al. The Pittsburgh agitation scale: A user-friendly instrument for rating agitation in dementia patients. The American Journal of Geriatric Psychiatry. 1994;2(1):52-9.
120. Cohen-Mansfield J, Marx MS, Rosenthal AS. A description of agitation in a nursing home. The Journals of Gerontology. 1989;44(3):M77-M84.
121. Parker D, Hodgkinson B. A comparison of palliative care outcome measures used to assess the quality of palliative care provided in long-term care facilities: a systematic review. Palliative Medicine. 2011;25(1):5-20.
122. van Soest-Poortvliet MC, van der Steen JT, Zimmerman S, Cohen LW, Klapwijk M, Bezemer M, et al. Psychometric properties of instruments to measure the quality of end-of-life care and dying for long-term care residents with dementia. Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation. 2012;21(4):671-84.
123. van Soest-Poortvliet MC, van der Steen JT, Zimmerman S, Cohen LW, Munn J, Achterberg WP, et al. Measuring the quality of dying and quality of care when dying in long-term care settings: a qualitative content analysis of available instruments. Journal of Pain and Symptom Management. 2011;42(6):852-63.
124. Evans CJ, Benalia H, Preston NJ, Grande G, Gysels M, Short V, et al. The selection and use of outcome measures in palliative and end-of-life care research: the MORECare international consensus workshop. Journal of Pain and Symptom Management. 2013; 46(6):925-937.
125. Volicer L, Hurley AC, Blasi ZV. Scales for evaluation of End-of-Life Care in Dementia. Alzheimer Disease & Associated Disorders. 2001;15(4):194-200.
126. Casarett D, Pickard A, Bailey FA, Ritchie CS, Furman CD, Rosenfeld K, et al. A nationwide VA palliative care quality measure: the family assessment of treatment at the end of life. Journal of Palliative Medicine. 2008;11(1):68-75.
127. Vohra JU, Brazil K, Hanna S, Abelson J. Family Perceptions of End-of-Life Care in long-term care facilities. Journal of Palliative Care. 2003;20(4):297-302.

128. Curtis JR, Patrick DL, Engelberg RA, Norris K, Asp C, Byock I. A measure of the quality of dying and death. Initial validation using after-death interviews with family members. Journal of Pain and Symptom Management. 2002;24(1):17-31.

129. Munn JC, Zimmerman S, Hanson LC, Williams CS, Sloane PD, Clipp EC, et al. Measuring the Quality of Dying in Long-Term Care. Journal of the American Geriatrics Society. 2007;55(9):1371-9.

130. Pang SM, Chan KS, Chung BP, Lau KS, Leung EM, Leung AW, et al. Assessing quality of life of patients with advanced chronic obstructive pulmonary disease in the end of life. Journal of Palliative Care. 2005;21(3):180-7.

131. Chan H, Pang S. Applicability of the modified Quality-of-Life Concerns in the End of Life Questionnaire (mQOLC-E) for frail older people. Asian Journal of Gerontology & Geriatrics. 2008;3(3):17-26.

132. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of Toolkit After-Death Bereaved Family Member Interview. Journal of Pain and Symptom Management. 2001;22(3):752-8.

133. Steel K, Ljunggren G, Topinkova E, Morris J, Vitale C, Parzuchowski J, et al. The RAI-PC: an assessment instrument for palliative care in all settings. American Journal of Hospice and Palliative Medicine. 2003;20(3):211-9.

134. Casarett D, Shreve S, Luhrs C, Lorenz K, Smith D, De Sousa M, et al. Measuring families' perceptions of care across a health care system: preliminary experience with the Family Assessment of Treatment at End of Life Short form (FATE-S). Journal of Pain and Symptom Management. 2010;40(6):801-9.

135. Biola H, Sloane PD, Williams CS, Daaleman TP, Williams SW, Zimmerman S. Physician Communication with Family Caregivers of Long-Term Care Residents at the End of Life. Journal of the American Geriatrics Society. 2007;55(6):846-56.

136. Aminoff BZ, Purits E, Noy S, Adunsky A. Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination. Archives of Gerontology and Geriatrics. 2004;38(2):123-30.

137. Zimmerman S, Cohen L, Reed D, Sloane P, Hanson L, Cagle J, et al. End of life in long term care in the United States: new findings and measurement issues. The Gerontologist. 2009;49(Supplement 2):58.

138. Schols R, Schipper R, Brabers A, Schols J. The Mini-Suffering State Exam (MSSE) has been studied in a Dutch nursing home. Tijdschrift voor Verpleeghuisgeneeskunde. 2003;27:14-8.
139. Cohen LW, Van Soest-Poortvliet M, Van der Steen J, de Vet HC, Reed D, Zimmerman S. Differences in the end-of-life experience in the United States and Netherlands. The Gerontologist. 2009;49(Suppl_2):58.
140. Aminoff BZ, Adunsky A. Dying dementia patients: too much suffering, too little palliation. American Journal of Hospice & Palliative Medicine. 2005;22(5):344-8.
141. Aminoff BZ, Adunsky A. Their last 6 months: suffering and survival of end-stage dementia patients. Age and Ageing. 2006;35(6):597-601.
142. Bausewein C, Fegg M, Radbruch L, Nauck F, von Mackensen S, Borasio GD, et al. Validation and clinical application of the german version of the palliative care outcome scale. Journal of Pain and Symptom Management. 2005;30(1):51-62.
143. Brandt HE, Deliens L, van der Steen JT, Ooms ME, Ribbe MW, van der Wal G. The last days of life of nursing home patients with and without dementia assessed with the Palliative care Outcome Scale. Palliative Medicine. 2005;19(4):334-42.
144. Cohen LW, van der Steen JT, Reed D, Hodgkinson JC, van Soest-Poortvliet MC, Sloane PD, et al. Family perceptions of end-of-life care for long-term care residents with dementia: differences between the United States and the Netherlands. Journal of the American Geriatrics Society. 2012;60(2):316-22.
145. Eisenchlas JH, Harding R, Daud ML, Perez M, De Simone GG, Higginson IJ. Use of the palliative outcome scale in Argentina: a cross-cultural adaptation and validation study. Journal of Pain and Symptom Management. 2008;35(2):188-202.
146. Kiely DK, Volicer L, Teno J, Jones RN, Prigerson HG, Mitchell SL. The validity and reliability of scales for the evaluation of end-of-life care in advanced dementia. Alzheimer Disease and Associated Disorders. 2006;20(3):176-81.
147. van der Steen JT, Gijsberts MJ, Muller MT, Deliens L, Volicer L. Evaluations of end of life with dementia by families in Dutch and U.S. nursing homes. International Psychogeriatrics. 2009;21(2):321-9.
148. van der Steen J, Gijsberts M, Knol D, Deliens L, Muller M. Ratings of symptoms and comfort in dementia patients at the end of life: Comparison of nurses and families. Palliative Medicine. 2009;23(4):317-24.

149. Volicer L, Hurley AC, Blasi ZV. Characteristics of dementia end-of-life care across care settings. American Journal of Hospice & Palliative Medicine. 2003;20(3):191-200.
150. Weiner MF, Martin-Cook K, Svetlik DA, Saine K, Foster B, Fontaine CS. The quality of life in late-stage dementia (QUALID) scale. Journal of the American Medical Directors Association. 2000;1(3):114-6.
151. Hurley A, Volicer B, Hanrahan P, Houde S, Volicer L. Assessment of discomfort in advanced Alzheimer patients. Research in Nursing & Health. 1992;15(5):369 - 77.
152. Warden V, Hurley AC, Volicer L. Development and Psychometric Evaluation of the Pain Assessment in Advanced Dementia (PAINAD) Scale. Journal of the Medical Directors Association. 2003;4(1):9-15.
153. Collins ES, Witt J, Bausewein C, Daveson BA, Higginson IJ, Murtagh FEM. A Systematic Review of the Use of the Palliative Care Outcome Scale and the Support Team Assessment Schedule in Palliative Care. Journal of Pain and Symptom Management. 2015;50(6):842-853.
154. Cicely Saunders Institute. Palliative care Outcome Scale: Cicely Saunders Institute; 2012. Available from: https://pos-pal.org/. Accessed 16 May 2017.
155. Harding R, Selman L, Agupio G, Dinat N, Downing J, Gwyther L, et al. Validation of a core outcome measure for palliative care in Africa: the APCA African Palliative Outcome Scale. Health and Quality of Life Outcomes. 2010;8:10.
156. Bausewein C, Le Grice C, Simon S, Higginson I. The use of two common palliative outcome measures in clinical care and research: A systematic review of POS and STAS. Palliative Medicine. 2011;25(4):304-13.
157. Dunckley M, Aspinal F, Addington-Hall JM, Hughes R, Higginson IJ. A research study to identify facilitators and barriers to outcome measure implementation. International Journal of Palliative Nursing. 2005;11(5):218-25.
158. Schildmann EK, Groeneveld EI, Denzel J, Brown A, Bernhardt F, Bailey K, et al. Discovering the hidden benefits of cognitive interviewing in two languages: The first phase of a validation study of the Integrated Palliative care Outcome Scale. Palliative Medicine. 2016;30(6):599-610.
159. Higginson IJ, Evans CJ, Grande G, Preston N, Morgan M, McCrone P, et al. Evaluating complex interventions in End of Life Care: the MORECare Statement on good practice

generated by a synthesis of transparent expert consultations and systematic reviews. BMC Medicine. 2013;11(1):111.

160. Hardeman W, Sutton S, Griffin S, Johnston M, White A, Wareham NJ, et al. A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. Health Education Research. 2005;20(6):676-87.
161. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. British Medical Journal. 2007;334(7591):455-9.
162. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. British Medical Journal. 2006;332(7538):413-6.
163. Campbell MJ, Donner A, Klar N. Developments in cluster randomized trials and Statistics in Medicine. Statistics in Medicine. 2007;26(1):2-19.
164. Shiell A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluation. British Medical Journal. 2008;336(7656):1281-3.
165. Hawe P, Shiell A, Riley T. Complex interventions: how “out of control” can a randomised controlled trial be? British Medical Journal. 2004;328(7455):1561-3.
166. Bumbarger B, Perkins D. After randomised trials: issues related to dissemination of evidence-based interventions. Journal of Children's Services. 2008;3(2):55-64.
167. Bonell C, Fletcher A, Morton M, Lorenc T, Moore L. Realist randomised controlled trials: a new approach to evaluating complex public health interventions. Social Science & Medicine. 2012;75(12):2299-306.
168. National Institutes of Health. NIH State-of-the-Science Conference Statement on improving end-of-life care. NIH consensus and state-of-the-science statements. 2004;21(3):1-26.
169. Gysels M, Evans CJ, Lewis P, Speck P, Benalia H, Preston NJ, et al. MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research. Palliative Medicine. 2013;27(10):908-17.
170. Preston NJ, Fayers P, Walters SJ, Pilling M, Grande GE, Short V, et al. Recommendations for managing missing data, attrition and response shift in palliative and end-of-life care research: Part of the MORECare research method guidance on statistical issues. Palliative Medicine. 2013; 27(10):899-907.
171. Farquhar M, Preston N, Evans CJ, Grande G, Short V, Benalia H, et al. Mixed Methods Research in the Development and Evaluation of Complex Interventions in Palliative and End-

of-Life Care: Report on the MORECare Consensus Exercise. Journal of Palliative Medicine. 2013;16(12):1550-60.

172. Preston N, Short V, Hollingworth W, McCrone P, Grande G, Evans C, et al. MORECare research methods guidance development: recommendations for health economic evaluations in palliative and end of life care research. Palliative Medicine. 2012;26(4):541.
173. Mental Capacity Act. London: HMSO; 2005.
174. Forbes S, Bern-Klug M, Gessert C. End-of-Life Decision Making for Nursing Home Residents with Dementia. Journal of Nursing Scholarship. 2000;32(3):251-8.
175. Anderson RA, Issel LM, McDaniel Jr RR. Nursing homes as complex adaptive systems: relationship between management practice and resident outcomes. Nursing Research. 2003;52(1):12.
176. Froggatt K, Davies S, Meyer J. Research and development in care homes: setting the scene. In: Froggatt K, Davies S, J. M, editors. Understanding Care Homes: A Research and Development Perspective. London: Jessica Kingsley Publishers; 2009. p. 9-22.
177. National Care Home Research and Development Forum. My Home Life - quality of life in care homes: a review of the literature. London: Help the Aged; 2007.
178. Goodman C, Davies SL, Dickinson A, Gage H, Froggatt K, Morbey H, et al. A study to develop integrated working between primary health care services and care homes. NIHR Service Delivery and Organisation programme. 2013.
179. Nilsen ES, Myrhaug HT, Johansen M, Oliver S, Oxman AD. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. Cochrane database of systematic reviews (Online). 2006;3. CD004563. Doi:10.1002/14651858.CD004563.pub2.
180. Creswell JW. Research design: Qualitative, quantitative, and mixed methods approaches. Los Angeles: Sage; 2009.
181. Miles MB, Huberman AM, Saldana J. Qualitative Data Analysis: a methods sourcebook. Third ed. Thousand Oaks, California: Sage Publications; 2014.
182. O'Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. BMC Health Services Research. 2007;7:85.
183. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research. 2nd ed. Thousand Oaks, California: Sage Publications; 2011.

184. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. British Medical Journal. 2010;341.
185. Foster RL. Addressing Epistemologic and Practical Issues in Multimethod Research: A Procedure for Conceptual Triangulation. Advances in Nursing Science. 1997;20(2):1-12.
186. Erzberger C, Prein G. Triangulation: Validity and empirically-based hypothesis construction. Quality and Quantity. 1997;31(2):141-54.
187. McEvoy P, Richards D. A critical realist rationale for using a combination of quantitative and qualitative methods. Journal of Research in Nursing. 2006;11(1):66-78.
188. Pawson R, Tilley N. Realistic evaluation. London: Sage Publications; 1997.
189. Bhaskar R. A Realist Theory of Science. London: Taylor & Francis Group; 2008.
190. Parlour R, McCormack B. Blending critical realist and emancipatory practice development methodologies: making critical realism work in nursing research. Nursing Inquiry. 2012;19(4):308-21.
191. Blackwood B, O'Halloran P, Porter S. On the problems of mixing RCTs with qualitative research: the case of the MRC framework for the evaluation of complex healthcare interventions. Journal of Research in Nursing. 2010;15(6):511-21.
192. Coyle J, Williams B. An exploration of the epistemological intricacies of using qualitative data to develop a quantitative measure of user views of health care. Journal of Advanced Nursing. 2000;31(5):1235-43.
193. Berger R. Now I see it, now I don't: researcher's position and reflexivity in qualitative research. Qualitative Research. 2015;15(2):219-34.
194. National Institute for Health Research. ENRICH: enabling research in care homes 2017 Available from: http://www.dendron.nihr.ac.uk/enrich/index.php. Accessed 1 September 2017.
195. Davies SL, Goodman C, Manthorpe J, Smith A, Carrick N, Iliffe S. Enabling research in care homes: an evaluation of a national network of research ready care homes. BMC Medical Research Methodology. 2014;14:47.
196. Froggatt K, Davies S, Meyer J. Understanding Care Homes: A research and development perspective. London: Jessica Kingsley Publishers; 2009.
197. Goodman C, Baron NL, Machen I, Stevenson E, Evans C, Davies SL, et al. Culture, consent, costs and care homes: enabling older people with dementia to participate in research. Aging & Mental Health. 2011;15(4):475-81.

198. Scott S, Jones L, Blanchard M, Sampson E. Study protocol: The behaviour and pain in dementia study (BePAID). BMC Geriatrics. 2011;11(1):61.

199. Handley M, Goodman C, Froggatt K, Mathie E, Gage H, Manthorpe J, et al. Living and dying: Responsibility for end-of-life care in care homes without on-site nursing provision - a prospective study. Health and Social Care in the Community. 2014;22(1):22-9.

200. Collins ES, Witt J, Bausewein C, Daveson BA, Higginson IJ, Murtagh FEM. A Systematic Review of the Use of the Palliative Care Outcome Scale and the Support Team Assessment Schedule in Palliative Care. Journal of Pain and Symptom Management. 2015;50(6):842-853.

201. De Roo ML, Albers G, Deliens L, de Vet HC, Francke AL, Van Den Noortgate N, et al. Physical and Psychological Distress Are Related to Dying Peacefully in Residents With Dementia in Long-Term Care Facilities. Journal of Pain and Symptom Management. 2015;50(1):1-8.

202. Black B, Finucane T, Baker A, Loreck D, Blass D, Fogarty L, et al. Health problems and correlates of pain in nursing home residents with advanced dementia. Alzheimer Disease & Associated Disorders. 2006;20(4):283 - 90.

203. Di Giulio P, Toscani F, Villani D, Brunelli C, Gentile S, Spadin P. Dying with advanced dementia in long-term care geriatric institutions: a retrospective study. Journal of Palliative Medicine. 2008;11(7):1023-8.

204. Lloyd-Williams M. An audit of palliative care in dementia. European Journal of Cancer Care. 1996;5(1):53-5.

205. Mitchell SL, Morris JN, Park PS, Fries BE. Terminal care for persons with advanced dementia in the nursing home and home care settings. Journal of Palliative Medicine. 2004;7(6):808-16.

206. Mitchell SL, Teno JM, Kiely DK, Shaffer ML, Jones RN, Prigerson HG, et al. The clinical course of advanced dementia. The New England Journal of Medicine. 2009;361(16):1529-38.

207. Brandt HE, Deliens L, Ooms ME, van der Steen JT, van der Wal G, Ribbe MW. Symptoms, signs, problems, and diseases of terminally ill nursing home patients: A nationwide observational study in the netherlands. Archives of Internal Medicine. 2005;165(3):314-20.

208. Sloane PD, Zimmerman S, Williams C, Hanson LC. Dying with dementia in long-term care. The Gerontologist. 2008;48(6):741-51.

209. Buchanan RJ, Choi M, Wang S, Huang C. Analyses of nursing home residents in hospice care using the minimum data set. Palliative Medicine. 2002;16(6):465-80.

210. Hall P, Schroder C, Weaver L. The last 48 hours of life in long-term care: a focused chart audit. Journal of the American Geriatrics Society. 2002;50(3):501-6.

211. Hanson LC, Eckert JK, Dobbs D, Williams CS, Caprio AJ, Sloane PD, et al. Symptom experience of dying long-term care residents. Journal of the American Geriatrics Society. 2008;56(1):91-8.

212. Reynolds K, Henderson M, Schulman A, Hanson LC. Needs of the dying in nursing homes. Journal of Palliative Medicine. 2002;5(6):895-901.

213. Parker D, Grbich C, Brown M, Maddocks I, Willis E, Roe P. A Palliative Approach or Specialist Palliative Care? What Happens in Aged Care Facilities for Residents With a Noncancer Diagnosis? Journal of Palliative Care. 2005;21(2):80-7.

214. Mor V, Angelelli J, Jones R, Roy J, Moore T, Morris J. Inter-rater reliability of nursing home quality indicators in the U.S. BMC Health Services Research. 2003;3:20.

215. Morris JN, Hawes C, Fries BE, Phillips CD, Mor V, Katz S, et al. Designing the national resident assessment instrument for nursing homes. The Gerontologist. 1990;30(3):293-307.

216. Hawes C, Morris JN, Phillips CD, Mor V, Fries BE, Nonemaker S. Reliability estimates for the Minimum Data Set for nursing home resident assessment and care screening (MDS). The Gerontologist. 1995;35(2):172-8.

217. Morris J, Murphy K, Nonemaker S. Long-term care resident assessment user's manual, version 2.0. Baltimore, MD: Health Care Financing Administration; 1995.

218. American Psychiatric Association. Diagnostic and statistical manual of mental disorders: Fourth Edition (DSM 4). American Psychiatric Association; 1994.

219. Robinson L, Dickinson C, Rousseau N, Beyer F, Clark A, Hughes J, et al. A systematic review of the effectiveness of advance care planning interventions for people with cognitive impairment and dementia. Age and Ageing. 2012;41(2):263-9.

220. Hemingway D, MacCourt P, Pierce J, Strudsholm T. Together but apart: Caring for a spouse with dementia resident in a care facility. Dementia. 2016;15(4):872-90.

221. Mullin J, Simpson J, Froggatt K. Experiences of spouses of people with dementia in long-term care. Dementia. 2013;12(2):177-91.

222. Detmar SB, Muller MJ, Schornagel JH, Wever LD, Aaronson NK. Health-related quality-of-life assessments and patient-physician communication. The Journal of the American Medical Association. 2002;288(23):3027-34.

223. Scholzel-Dorenbos C, Ettema T, Bos J, Boelens-van der Knoop E, Gerritsen D, Hoogeveen F, et al. Evaluating the outcome of interventions on quality of life in dementia: selection of the appropriate scale. International Journal of Geriatric Psychiatry. 2007;22(6):511 - 9.

224. Selai C, Trimble MR. Assessing quality of life in dementia. Aging & Mental Health. 1999;3(2):101-11.

225. Algar K, Woods RT, Windle G. Measuring the quality of life and well-being of people with dementia: A review of observational measures. Dementia. 2016;15(4):832-57.

226. Malley JN, Towers AM, Netten AP, Brazier JE, Forder JE, Flynn T. An assessment of the construct validity of the ASCOT measure of social care-related quality of life with older people. Health and Quality of Life Outcomes. 2012;10:21.

227. Rand S, Caiels J, Collins G, Forder J. Developing a proxy version of the Adult social care outcome toolkit (ASCOT). Health and Quality of Life Outcomes. 2017;15(1):108.

228. Langlois A, Anderson DE. Resolving the quality of life/well-being puzzle: toward a new model. The Canadian Journal of Regional Science. 2002;25(3):501-11.

229. Burgener SC, Twigg P, Popovich A. Measuring psychological well-being in cognitively impaired persons. Dementia. 2005;4(4):463-85.

230. Lawton MP, Van Haitsma K, Klapper J. Observed affect in nursing home residents with Alzheimer's disease. Journal of Gerontology: Psychological Sciences. 1996; 51B(1):3-14.

231. Kolanowski A, Hoffman L, Hofer SM. Concordance of self-report and informant assessment of emotional well-being in nursing home residents with dementia. Journal of Gerontology: Psychological Sciences and Social Sciences. 2007;62(1):20-7.

232. Snyder M, Ryden MB, Shaver P, Wang J, Savik K, Gross CR, et al. The Apparent Emotion Rating Instrument: assessing affect in cognitively impaired elders. Clinical Gerontologist. 1998;18(4):17-29.

233. Lawton MP, Van Haitsma K, Perkinson M, Ruckdeschel K. Observed affect and quality of life in dementia: Further affirmations and problems. Journal of Mental Health and Aging. 1999; 5(1):69-81.

234. Perrin T. The Positive Response Schedule for Severe Dementia. Aging & Mental Health. 2010; 1(2):184-191.

235. Bradford Dementia Group. The Bradford Well-being Profile. Bradford: University of Bradford; 2008.
236. Rentz CA. Memories in the making: outcome-based evaluation of an art program for individuals with dementing illnesses. American Journal of Alzheimer's Disease & Other Dementias. 2002;17(3):175-81.
237. Brooker DJ, Surr C. Dementia Care Mapping (DCM): initial validation of DCM 8 in UK field trials. International Journal of Geriatric Psychiatry. 2006;21(11):1018-25.
238. Brooker D. Dementia care mapping: a review of the research literature. Gerontologist. 2005;45 Spec No 1(1):11-8.
239. University of Bradford. Introduction to Dementia Care Mapping (DCM); 2015. Available from:http://www.bradford.ac.uk/health/dementia/dementia-care-mapping/file-downloads/Introduction-to-Dementia-Care-Mapping.pdf. Accessed 3 July 2017.
240. Kaufmann EG, Engel SA. Dementia and well-being: A conceptual framework based on Tom Kitwood's model of needs. Dementia. 2016;15(4):774-88.
241. Oxford University Press. English Oxford Living Dictionaries 2017. Available from: https://en.oxforddictionaries.com/definition/need. Accessed 7 July 2017.
242. Maslow AH. A theory of human motivation. Psychol Rev. 1943;50(4):370-96.
243. Hancock G, Orrell M. Introduction. In: Orrell M, Hancock G, editors. CANE - Camberwell Assessment of Need for the Elderly: A needs assessment for older mental health service users. London: Gaskell 2004.
244. Stevens A, Gillam S. Needs assessment: from theory to practice. British Medical Journal. 1998;316(7142):1448-52.
245. Higginson IJ, Hart S, Koffman J, Selman L, Harding R. Needs Assessments in Palliative Care: An Appraisal of Definitions and Approaches Used. Journal of Pain and Symptom Management. 2007;33(5):500-5.
246. Orrell M, Hancock G. CANE: Camberwell assessment of need for the elderly: Gaskell London; 2004.
247. Reynolds T, Thornicroft G, Abas M, Woods B, Hoe J, Leese M, et al. Camberwell Assessment of Need for the Elderly (CANE). Development, validity and reliability. British Journal of Psychiatry. 2000;176:444-52.
248. Reynolds T, Hancock G, Woods B, Thornicroft G, Orrell M. Development of the Camberwell Assessment of Need for the Elderly (CANE). In: Orrell M, Hancock G, editors. CANE -

Camberwell Assessment of Need for the Elderly: A needs assessment for older mental health service users. London: Gaskell; 2004.

249. Hancock G, Orrell M. CANE instruction manual. In: Orrell M, Hancock G, editors. CANE - Camberwell Assessment of Need for the Elderly: A needs assessment for older mental health service users. London: Gaskell; 2004.
250. Kovach CR, Noonan PE, Griffie J, Muchka S, Weissman DE. The assessment of discomfort in dementia protocol. Pain Management Nursing. 2002;3(1):16-27.
251. Kovach CR, Logan BR, Noonan PE, Schlidt AM, Smerz J, Simpson M, et al. Effects of the Serial Trial Intervention on discomfort and behavior of nursing home residents with dementia. American Journal of Alzheimer's Disease & Other Dementias. 2006;21(3):147-55.
252. Cohen-Mansfield J, Libin A. Verbal and physical non-aggressive agitated behaviors in elderly persons with dementia: robustness of syndromes. Journal of Psychiatric Research. 2005;39(3):325-32.
253. Testad I, Aasland AM, Aarsland D. Prevalence and correlates of disruptive behavior in patients in Norwegian nursing homes. International Journal of Geriatric Psychiatry. 2007;22(9):916-21.
254. National Institute for Health and Clinical Excellence/Social Care Institute for Excellence. Dementia: Supporting people with dementia and their carers in health and social care; 2011. Available from: http://www.nice.org.uk/nicemedia/live/10998/30320/30320.pdf. Accessed 14 July 2017.
255. Cohen-Mansfield J. Assessment of agitation. International Psychogeriatrics. 1996;8(2):233-45.
256. Masso M, Allingham SF, Banfield M, Johnson CE, Pidgeon T, Yates P, et al. Palliative Care Phase: inter-rater reliability and acceptability in a national study. Palliative Medicine. 2015;29(1):22-30.
257. Powell C, Blighe A, Froggatt K, McCormack B, Woodward-Carlton B, Young J, et al. Family involvement in timely detection of changes in health of nursing homes residents: a qualitative exploratory study. Journal of Clinical Nursing. 2018; 27(1-2):317-327.
258. Hennings J, Froggatt K, Payne S. Spouse caregivers of people with advanced dementia in nursing homes: a longitudinal narrative study. Palliative Medicine. 2013;27(7):683-91.

259. van der Steen JT, Lemos Dekker N, Gijsberts MHE, Vermeulen LH, Mahler MM, The BA. Palliative care for people with dementia in the terminal phase: a mixed-methods qualitative study to inform service development. BMC Palliative Care. 2017;16(1):28.

260. Goodman C, Dening T, Gordon AL, Davies SL, Meyer J, Martin FC, et al. Effective health care for older people living and dying in care homes: a realist review. BMC Health Services Research. 2016;16(1):1-14.

261. Antunes B, Harding R, Higginson IJ. Implementing patient-reported outcome measures in palliative care clinical practice: a systematic review of facilitators and barriers. Palliative Medicine. 2014;28(2):158-75.

262. Kinley J, Stone L, Dewey M, Levy J, Stewart R, McCrone P, et al. The effect of using high facilitation when implementing the Gold Standards Framework in Care Homes programme: A cluster randomised controlled trial. Palliative Medicine. 2014;28(9):1099-109.

263. Hockley J, Watson J, Oxenham D, Murray S. The integrated implementation of two end-of-life care tools in nursing care homes in the UK: an in-depth evaluation. Palliative Medicine. 2010;24(8):828-38.

264. O'Reilly M, Larkin P, Conroy M, Twomey F, Lucey M, Dunne C, et al. The Impact of a Novel Tool for Comprehensive Assessment of Palliative Care (MPCAT) on Assessment Outcome at 6- and 12-Month Follow-Up. Journal of Pain and Symptom Management. 2016;52(1):107-16.

265. Froggatt K, Davies S, Atkinson L, Aveyard B, Binney S, Kent Y, et al. The joys and tribulations of partnership working in care homes for older people. Quality in Ageing and Older Adults. 2006;7(3):26-32.

266. DiazOrdaz K, Slowther A-M, Potter R, Eldridge S. Consent processes in cluster-randomised trials in residential facilities for older adults: a systematic review of reporting practices and proposed guidelines. BMJ Open. 2013;3(7):e003057.

267. Hall S, Longhurst S, Higginson IJ. Challenges to conducting research with older people living in nursing homes. BMC Geriatrics. 2009;9(1):38.

268. Evans C, Goodman C. Changing practice in dementia care for people in care homes towards the end of life. Dementia. 2009;8(3):424-31.

269. Zermansky AG, Alldred DP, Petty DR, Raynor DK. Striving to recruit: the difficulties of conducting clinical research on elderly care home residents. Journal of the Royal Society of Medicine. 2007;100(6):258-61.

270. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist manual. Amsterdam: VU University Medical Center. 2009.

271. Abernethy AP, Shelby-James T, Fazekas BS, Woods D, Currow DC. The Australia-modified Karnofsky Performance Status (AKPS) scale: a revised scale for contemporary palliative care clinical practice]. BMC Palliative Care. 2005;4(1):7.

272. Simon ST, Higginson IJ, Harding R, Daveson BA, Gysels M, Deliens L, et al. Enhancing patient-reported outcome measurement in research and practice of palliative and end-of-life care. Supportive Care in Cancer. 2012;20(7):1573-8.

10. Appendices

Appendix A. Scoping review methods

Aim:

To identify palliative care measures developed for or used with people with dementia, to gain an understanding of the construct of palliative care for people with dementia including domains assessed, and to identify the populations of dementia that palliative care measures are used for including dementia severity and settings.

Methods:

The Cochrane Library, PsycINFO and EMBASE were searched in July 2012 using terms palliative care AND dementia OR Alzheimer's disease AND outcome OR measurement OR assessment for articles published in the last ten years. Reference and citation searches of included articles were conducted using Scopus. Systematic reviews or original articles that reported the development, psychometric evaluation or use of palliative care measures in people with dementia in any care setting were included. Measures were those used to assess palliative care need or measure palliative care outcomes, including those that assessed multiple or individual symptoms and concerns, quality of care, and carers' concerns. Conference abstracts and theses were excluded. As this was a scoping review to determine established measures used in dementia, grey literature was not searched. Titles and abstracts were reviewed by one reviewer and those clearly not meeting the inclusion criteria were excluded. The remaining full texts were reviewed by one reviewer to determine whether the articles met the inclusion criteria.

One reviewer extracted all the data. Data extraction included (1) lead author and date of publication, (2) study design, (3) name of measure(s), (4) construct(s) of the measure(s), (5) population (including dementia stages) and setting, (6) any details of original development of measure including original reference, and population that measure was originally developed for. As the aim of the review was to identify what palliative care measures had been used for people with dementia, and not the strengths of these measures, quality assessment of the articles was not conducted.

Appendix B. The Palliative care Outcome Scale, POS-Symptom and Integrated Palliative care Outcome Scale

Palliative care Outcome Scale
STAFF QUESTIONNAIRE (version 1)

www.pos-pal.org

Patient name: ……Assessment date: .....

Date of birth: ……Assessment no: ……..

Care setting: ……

Please answer the following questions by ticking the box next to the answer that you think most accurately describes how the patient has been feeling.
Thank you.

1 Over the past 3 days, has the patient been affected by pain?

- ❑ 0 Not at all, no effect
- ❑ 1 Slightly - but not bothered to be rid of it
- ❑ 2 Moderately - pain limits some activity
- ❑ 3 Severely - activities or concentration markedly affected
- ❑ 4 Overwhelmingly - unable to think of anything else

2 Over the past 3 days, have other symptoms e.g. nausea, coughing or constipation seemed to be affecting how they feel?

- ❑ 0 No, not at all
- ❑ 1 Slightly
- ❑ 2 Moderately
- ❑ 3 Severely
- ❑ 4 Overwhelmingly

3 Over the past 3 days, has s/he been feeling anxious or worried about their illness or treatment?

- ❑ 0 No, not at all
- ❑ 1 Occasionally
- ❑ 2 Sometimes - affects their concentration now and then
- ❑ 3 Most of the time - often affects their concentration
- ❑ 4 The patient does not seem to think of anything else - completely pre-occupied by worry and anxiety

4 Over the past 3 days, have any of their family or friends been anxious or worried about the patient?

- ❑ 0 No, not at all
- ❑ 1 Occasionally
- ❑ 2 Sometimes – it seems to affect their concentration
- ❑ 3 Most of the time
- ❑ 4 Yes, they always seem preoccupied with worry

5 Over the past 3 days, how much information has been given to the patient and their family or friends?

- ❑ 0 Full information or as much as wanted – always feel free to ask
- ❑ 1 Information given but hard to understand
- ❑ 2 Information given on request but would have liked more
- ❑ 3 Very little given and some questions were avoided
- ❑ 4 None at all – when they wanted information

6 Over the past 3 days, has the patient been able to share how they are feeling with their family or friends?

- ❑ 0 Yes, as much as they wanted to
- ❑ 1 Most of the time
- ❑ 2 Sometimes
- ❑ 3 Occasionally
- ❑ 4 No, not at all with anyone

7 Over the past 3 days, do you think they felt that life was worth living?

- ❑ 0 Yes, all the time
- ❑ 1 Most of the time
- ❑ 2 Sometimes
- ❑ 3 Occasionally
- ❑ 4 No, not at all

8 Over the past 3 days, do you think s/he has felt good about themselves?

- ❑ 0 Yes, all the time
- ❑ 1 Most of the time
- ❑ 2 Sometimes
- ❑ 3 Occasionally
- ❑ 4 No, not at all

9 Over the past 3 days, how much time do you feel has been wasted on appointments relating to the healthcare of this patient, e.g. waiting around for transport or repeating tests?

- ❑ 0 None at all
- ❑ 2 Up to half a day wasted
- ❑ 4 More than half a day wasted

10 Over the past 3 days, have any practical matters resulting from their illness, either financial or personal, been addressed?

- ❑ 0 Practical problems have been addressed and their affairs are as up to date as they would wish
- ❑ 2 Practical problems are in the process of being addressed
- ❑ 4 Practical problems exist which were not addressed
- ❑ 0 The patient has had no practical problems

11 If any, what have been the patient's main problems in the last 3 days?

1. .....

2. .....

12 What is the patient's ECOG scale performance status?

- ❑ 0 Fully active
- ❑ 1 Restricted
- ❑ 2 Ambulatory
- ❑ 3 Limited self care
- ❑ 4 Completely disabled

POS-S – PATIENT COMPLETION

Below is a list of symptoms, which you may or may not have experienced. Please put a tick in the box to show how you feel each of these symptoms has affected you and how you been feeling over the **past week.**

	Not at all No effect	**Slightly** but not bothered to be rid of it	**Moderately** limits some activity or concentration	**Severely** activities or concentration markedly affected	**Overwhelmingly** unable to think of anything else
Pain	☐0	☐1	☐2	☐3	☐4
Shortness of breath	☐0	☐1	☐2	☐3	☐4
Weakness or lack of energy	☐0	☐1	☐2	☐3	☐4
Nausea (feeling like you are going to be sick)	☐0	☐1	☐2	☐3	☐4
Vomiting (being sick)	☐0	☐1	☐2	☐3	☐4
Poor appetite	☐0	☐1	☐2	☐3	☐4
Constipation	☐0	☐1	☐2	☐3	☐4
Mouth problems	☐0	☐1	☐2	☐3	☐4
Drowsiness	☐0	☐1	☐2	☐3	☐4
Immobility	☐0	☐1	☐2	☐3	☐4
Any other symptoms:					
	☐0	☐1	☐2	☐3	☐4
	☐0	☐1	☐2	☐3	☐4
	☐0	☐1	☐2	☐3	☐4

Which symptom has affected you the most? _____

Which symptom has improved the most? _____

POS-S v1_P_En_16052011

POS-S

Palliative care Outcome Scale - Symptoms

NAME:

PATIENT NUMBER:

www.pos-pal.org
www.csi.kcl.ac.uk

Please write clearly, one letter or digit per box.

IPOS Staff Version

www.pos-pal.org

Patient name: .....

Patient number:

Date (dd/mm/yyyy): / /

Q1. What have been the patient's main problems over the past week?

1. _____

2. _____

3. _____

Q2. Please tick one box that best describes how the patient has been affected by each of the following symptoms over the past week?

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot assess (e.g. unconscious)*
Pain	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Shortness of breath	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weakness or lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Nausea (feeling like you are going to be sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Vomiting (being sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor appetite	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Constipation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Sore or dry mouth	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Drowsiness	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor mobility	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please list any other symptoms and tick one box to show how you feel each of these symptoms has affected the patient over the past week.

1. _____	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
2. _____	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
3. _____	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Over the past week:

	Not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Always*	*Cannot assess (e.g. unconscious)*
Q3. Has s/he been feeling anxious or worried about his/her illness or treatment?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q4. Have any of his/her family or friends been anxious or worried about the patient?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q5. Do you think s/he felt depressed?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

	Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*	*Cannot assess (e.g. unconscious)*
Q6. Do you think s/he has felt at peace?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q7. Has the patient been able to share how s/he is feeling with his/her family or friends as much as s/he wanted?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q8. Has the patient had as much information as s/he wanted?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

	Problems addressed/ No problems	*Problems mostly addressed*	*Problems partly addressed*	*Problems hardly addressed*	*Problems not addressed*	*Cannot assess (e.g. unconscious)*
Q9. Have any practical problems resulting from his/her illness been addressed? (such as financial or personal)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Appendix C. PPI letter of support for ethics committee

Reprinted with author's permission

Ethics Committee letter

Gill Peters, 12/08/13

I am writing in support of an application by Clare Ellis–Smith to conduct the following study:, The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes.'

I was approached to participate in the OptCare research project following the death of my mother from advanced vascular dementia in early 2012. I did not become involved in that project, but I did contact Dr. Catherine Evans to express my concern that a survey specifically targeted at the palliative care of patients with advanced dementia was needed. As a result I was invited to the Cicely Saunders Institute to meet with her and Clare to discuss a new research project examining the special nature of palliative care of people with dementia in the care home setting.

My mother was diagnosed with vascular dementia while in her late seventies, and following the death of my father (her carer) in 2007 moved first to a residential care home and then, a year later, to an EMI nursing home close to my home where she spent the last six years of her life. Physically healthy, she suffered no major illness but over time lost the ability to speak coherently or to walk, and, finally, to move at all. In the latter few years she was hospitalised several times to receive intravenous antibiotics and rehydration due to recurrent urinary tract infections. These were difficult to diagnose as she did not display any discomfort and was doubly incontinent, making the sampling of urine virtually impossible. She also had a number of falls over time including one resulting in a broken hip which was not immediately diagnosed, not least because she gave no outward sign of pain, discomfort or indeed any distress. I still have no idea whether she was in fact experiencing pain on all these occasions, but was just incapable of expressing it.

I found the discussion with Catherine and Clare extremely rewarding, as I believe that they are sincere in wanting to explore the issues surrounding our treatment of those with dementia and consequently improve their care. They asked if I would like to be involved in the planning of this particular project as someone with experience of taking responsibility for a close relative with dementia, and I was happy to agree. I have subsequently been invited to comment on the draft protocol and supporting documentation relating to the resident participants and family/friend participants. Clare has taken care to respond to all my concerns and queries, and my suggested changes to make the supporting documentation more accessible to those being asked to give consent on behalf of friends/relatives have, where possible, been taken into account.

I have looked at all the documentation from the standpoint of a consultee, imagining I was considering whether to recommend my mother as a study participant. I have come to the conclusion that I would definitely be in favour, particularly if I could be involved in a focus group in which I could make an active contribution to the content and application of the POS-Dem questionnaire. I also think that the care home staff would benefit. In my experience when a resident has reached a fairly advanced stage of dementia the staff find it more difficult to look past the inertia and lack of responsiveness and still see the person within. The POS-

Dem approach depends on the resident being assessed very much as an individual with specific needs and concerns, and this may improve the relationship between carer and resident.

Cancer was once a taboo subject, and not discussed openly. My father refused to allow the words ‘dementia’ or ‘Alzheimer’s’ to be mentioned in front of my mother, and did not discuss her condition with friends or any other members of the family. We need to break down the barriers and confront our fears, especially given the sheer numbers of people who are going to end their days as dementia sufferers in the future (and I speak as a baby boomer considering her own future and that of her contemporaries). This study may provide valuable insight into how pain and other physical and psychological symptoms can be assessed in this most vulnerable group of people despite difficulties of communication, and thereby meet a definite clinical need. I am happy to lend my support to this initiative in the hope that it will contribute towards meeting this aim.

Yours sincerely

Appendix D. Example letter of approach to care home provider

School of Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson
BMedSci BMBS FFPHM PhD FRCP
Head of Department
Professor Lynne Turner-Stokes
DM FRCP
Herbert Dunhill
Chair of Rehabilitation

Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ
Tel: +44 (0)20 7848 5516
Fax: +44 (0)20 7848 5517
www.kcl.ac.uk/palliative

KING'S College LONDON

12 June 2013
[Name]
[Address]

Dear [Name]

Re: Research project on palliative care for people with dementia in residential care homes – [Name of care home]

I am an occupational therapist with a clinical background in older adult mental health, and a special interest in dementia. I successfully applied for a position to undertake a PhD in palliative care in dementia at the Cicely Saunders Institute, King's College London, supervised by Dr Barbara Daveson, Dr Catherine Evans and Professor Irene Higginson. [Name], Nurse Consultant at St Christopher's Hospice, has given me the name of [Name of care home] and suggested that the staff in this care home may be interested in participating in a research project. I understand from the CQC website, that you are the person responsible for this care home and am therefore writing to you about this potential opportunity.

We know that throughout the world people with dementia have difficulties in accessing palliative care. This is in part due to people with dementia having poor communication abilities and therefore having problems in expressing need. Additionally, there are a lack assessment tools and interventions to aid access to palliative care for people with dementia. As cognitive impairment is a primary reason for people moving into care homes, care home staff are frequently the people best placed to identify palliative care need and communicate this need to primary healthcare professionals.

The aim of my project is to develop an intervention that can help care home staff identify palliative care need and use this to work with GPs and community nurses. Developing such an intervention requires the expertise and input of care home staff and I would therefore like to work with two care homes in the [Name of London borough] for the duration of the project. I envisage that the staff of care homes participating in this project may be involved in the following ways:

- Participating in focus groups and/or interviews to help the development of the intervention
- Identifying residents who would be eligible to participate in the intervention
- Implementing the intervention for a period of six months – this is likely to entail completing an assessment measure on a monthly basis and using the measure to discuss need with GPs and district nurses as necessary
- Participating in focus groups at the end of the intervention to provide feedback on whether the intervention has been useful and practical to use

This will be an exciting opportunity to collaborate on the development and piloting of a novel intervention for residential care homes. I envisage that, on completion of the project, the intervention will be implemented and tested more widely. It is proposed that the study will be on the National Institute of Health Research Clinical Research Network (NIHR CRN) portfolio and it will get approval from a NIHR research ethics committee and the local authority before commencing.

I would be delighted if I could speak with you to discuss this project and the possibility of [Name of care home] participating in it; and, with your permission, approach the manager of [Name of care home]. I would therefore like to contact you by telephone over the next few weeks and am writing to you prior to this in order to introduce myself. If you have any queries and would like to speak with me prior to my phone call, please do not hesitate to contact me on:

Telephone: 020 78485434
E-mail: alexandra.c.ellis-smith@kcl.ac.uk

I look forward to speaking to you and the potential opportunity of working with you in the future.

Yours sincerely

Clare Ellis-Smith
BSc Occupational Therapy, MSc
BuildCARE PhD Training Felllow

Appendix E. Ethics application, amendments and approvals

NHS REC Form | Reference: 13/LO/1339 | IRAS Version 3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
A palliative care intervention for people with dementia in care homes

1. Is your project research?

◉ Yes ○ No

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
○ Basic science study involving procedures with human participants
◉ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Study involving qualitative methods only
○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
○ Study limited to working with data (specific project only)
○ Research tissue bank
○ Research database

If your work does not fit any of these categories, select the option below:

○ Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	◉ No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	◉ No
c) Will you be using existing human tissue samples (or other human biological samples)?	○ Yes	◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

(●) Yes ( ) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

( ) Yes (●) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

(●) Yes ( ) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
Clare Ellis-Smith will be involved in the design, recruitment and carrying out the research.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NHS REC Form | Reference: 13/LO/1339 | IRAS Version 3.5

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

NHS
Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
A palliative care intervention for people with dementia in care homes

Please complete these details after you have booked the REC application for review.

REC Name:
NRES Committee London - South East

REC Reference Number:
13/LO/1339

Submission date:
15/08/2013

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Ms	Clare	Ellis-Smith
Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
Post Code	SE5 9PJ		
E-mail	alexandra.c.ellis-smith@kcl.ac.uk		
Telephone	02078485434		
Fax	02078485517		

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
PhD in palliative care

Name of educational establishment:
King's College London

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Barbara	Daveson
Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
Post Code	SE5 9PJ		
E-mail	barbara.daveson@kcl.ac.uk		
Telephone	02078485565		
Fax	02078485517		

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Catherine	Evans
Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
Post Code	SE5 9PJ		
E-mail	catherine.evans@kcl.ac.uk		
Telephone	02078485579		
Fax	02078485517		

Academic supervisor 3

	Title	Forename/Initials	Surname
	Professor	Irene	Higginson
Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
Post Code	SE5 9PJ		
E-mail	irene.higginson@kcl.ac.uk		
Telephone	02078485516		
Fax	02078485517		

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Ms Clare Ellis-Smith	☑ Dr Barbara Daveson

☑ Dr Catherine Evans

☑ Professor Irene Higginson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

○ Student
◉ Academic supervisor
○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Barbara	Daveson
Post	Research Fellow		
Qualifications	PhD, BMus (MUSTHY)		
Employer	King's College London		
Work Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
Post Code	SE5 9PJ		
Work E-mail	barbara.daveson@kcl.ac.uk		
* Personal E-mail	barbara.daveson@kcl.ac.uk		
Work Telephone	02078485565		
* Personal Telephone/Mobile			
Fax	02078485517		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Keith	Brennan
Address	Room 1.8 Hodgkin Building		
	King's College London, Guy's Campus		
	Great Maze Pond, London		
Post Code	SE1 4UL		
E-mail	keith.brennan@kcl.ac.uk		
Telephone	02078486960		
Fax	02078486394		

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

◯ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

The aim of this study is to develop an intervention, the Palliative care Outcome Scale for Dementia (POS-Dem). In addition, we aim to establish how useful and acceptable POS-Dem is as an intervention, and understand how it works in practice. POS-Dem will be an instrument to aid residential care home staff identify and monitor palliative care problems in people with dementia, and communicate these to primary healthcare staff. It is proposed that it will improve symptom management and quality of life for this group of residents.

There are three phases to the study. In phase one, we will review existing literature in order to adapt an established outcome measure, the Palliative care Outcome Scale (POS), for use with people with dementia in residential care homes. Guidance and training on how to use POS-Dem will also be developed in this phase.

Phase two will involve focus groups and interviews with families/friends of residents, care home staff, GPs and district nurses. They will be analysed and we will use the results to establish what items are important for inclusion, and how well users understand and interpret POS-Dem. Any necessary adaptations to POS-Dem will then be made.

The final phase will involve a four-month implementation of POS-Dem in three care homes. POS-Dem will be used by care home staff for up to 65 residents with dementia. This phase will be used to establish the measurement properties of POS-Dem. Additionally, at the end of the implementation, focus groups will be carried out with family/friends of residents, care home staff, GPs and district nurses in order to establish the acceptability of POS-Dem and its feasibility for use in routine care. Finally, through examination of case notes and participant-observation, we can gain an understanding of how POS-Dem works in practice.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified

and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

HOW WILL RESIDENTS BE RECRUITED TO TAKE PART IN THE STUDY?

This study will adhere to the Mental Capacity Act for recruiting people with impaired capacity to the study. An adapted recruitment protocol used by Scott et al.(2011)will be used to recruit residents (see supporting documents for flowchart). Initially posters will be displayed in all the participating care homes with details of the project and a photograph of the doctoral student. A coffee morning or similar event can be held with residents, family and friends in order to provide information about the study. This will provide the opportunity for unpaid carers and residents to request more information and ask questions about the study. It will also give the opportunity for unpaid carers to request, if they wish, that their family member or friend is not approached, and for residents to decline participation.

The care home manager will then be asked to identify all eligible residents who have not declined and introduce them to members of the research team for eligibility screening. A member of the research team will meet with each participant to determine whether they meet the eligibility criteria according to the Global Deterioration Scale (Reisberg et al. 1982). If the participant does meet the eligiblity criteria and is willing to discuss the project, a member of the research team will go through the study with them using a single-page information sheet. A capacity assessment will be carried out at this time in order to determine whether the residents can (i) comprehend the information provided, (ii) retain this information in order to make an informed decision, and (iii) communicate the decision to the research team member (Mental Capacity Act 2005). The information sheet along with a more detailed patient information sheet will be left with the resident for a period one week (or more if requested) in order to provide the opportunity for family members to review the information with the residents. A member of the research team will return after this time to gain written consent.

It is likely that many of the participants will lack capacity to consent or have fluctuating capacity, and those that are able to provide consent may lose capacity over the study period. Gysels et al. recommend a 'belts and braces' approach to recruiting people who may lose capacity in England and suggest that advice from a consultee should be obtained at the same time as consent. For each resident who consents and each resident who does not have capacity, a personal consultee will be approached to obtain advice. The care home manager will be asked whether there is any person who the resident has chosen as someone to make decisions their behalf. If this person is not being paid as a professional in this capacity (e.g. GP or solicitor), they will be requested to act as a personal consultee. Personal consultees will be written to with details of the study and an explanation of what the role of personal consultee entails. Personal consultees will be offered the opportunity to meet with the researcher to discuss the project and to arrange for the consent form to be signed.

At least two attempts over a period of three weeks will be provided in order to gain contact from personal consultees. After this time, or in the case where there is no personal consultee or the personal consultee lives far away, the professional consultee will be approached. The nominated professional consultee will have a good working knowledge of research but be independent from the study.

WILL ALL PATIENTS WITH DEMENTIA OR COGNITIVE IMPAIRMENT BE RECRUITED REGARDLES OF DISEASE SEVERITY?

In order to ensure that the intervention can be used with a wide a range of people with cognitive impairment or dementia, we would like to include participants in all stages of dementia. All residents who have a formal diagnosis of dementia (any stage) will therefore be eligible. Potential cognitive impairment will initially be determined by care home staff and the knowledge they have of the resident, and then through interview with a member of the research team determined by the Global Deterioration scale stages four to seven (Reisberg et al. 1982).

HOW WILL UNPAID CARERS BE RECRUITED TO TAKE PART IN THE STUDY?

The study will be advertised through posters in the care homes. A coffee morning will be arranged in collaboration with the care home manager in order to provide information to family and friends. Interested unpaid carers will be given information leaflets about the study. The care home manager will be asked to approach eligible family or friends who were not able to attend the meeting to request whether they would be prepared to be contacted by the researcher. If in agreement, the researcher will meet and discuss the project with them, or post information leaflets to them. Written information about the study will be provided at least 24 hours before written consent is obtained. In order to minimise the time involved for unpaid carers, written consent will be obtained at the same time as participation in the focus groups.

HOW WILL CARE HOME STAFF, GPs AND DISTRICT NURSES BE RECRUITED TO THE STUDY?

Once care homes, GP surgeries and district nursing teams have been identified, individual staff will be given information about the whole study and what it entailed in each phase of the study. Participant information sheets will also be given to each paid professional who participates but in order to minimise the time involved for them, this will be provided at the same time as written consent is obtained at the time of the focus groups or interviews.

ARE THERE ANY RISKS TO INDIVIDUALS SURROUNDING THIS STUDY, AND WHAT STEPS HAVE BEEN TAKEN TO PREVENT THIS?

We have sought a design that is as minimally intrusive as possible for people with dementia who may be frail with comordities. As such, it is not anticipated that this study will cause distress or burden to resident participants. The intervention is designed to improve symptom management and quality of life for people with dementia but it is not tested and it is therefore not known whether there will be any benefit from receiving the intervention. As POS-Dem has not yet been validated, there is a small risk that it could result in increased unnecessary investigations. However, this intervention will NOT replace professionals' clinical judgment about resident care needs. It is therefore not anticipated that a resident will be referred for any investigation or treatment that is not required. Instead, it is proposed that this study will alert professionals to potential need, therefore allowing decisions to be made about best care.

When working with vulnerable adults, there is a potential of uncovering safeguarding vulnerable adult concerns. In this event, local policies and procedures will be followed for reporting these. In this case, [redacted] Council has a safeguarding vulnerable adult contact number for both office hours and out-of-hours for urgent cases. All participants, whether professional, residents or families, will be advised in the study information leaflet that confidentiality will be maintained at all times. It will also be explained that in the unlikely event that a vulnerable person may be at risk of harm, or if any unsafe practice is revealed then confidentiality be broken and local policies for reporting will need to be followed.

There is some risk that family and friends may find the process of discussing the care of their loved ones distressing. They will have the option of omitting to answer any particular question, or to withdraw from the study at any time without giving reasons why.

It will be made clear that taking part will not affect participant's care or healthcare management in any way. Participants will be informed of this as part of the consenting process.

REFERENCES:

Gysels, M., Evans, C. J., Lewis, P., Speck, P., Benalia, H., Preston, N. J., Grande, G. E., Short, V., Owen-Jones, E. and Todd, C. J. (2013) 'MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research', Palliative Medicine.

Mental Capacity Act (2005) Chapter 9, London: HMSO.

Reisberg, B., Ferris, S. H., de Leon, M. J. and Crook, T. (1982) 'The Global Deterioration Scale for assessment of primary degenerative dementia', The American journal of psychiatry, 139(9), 1136-1139.

Scott, S., Jones, L., Blanchard, M. and Sampson, E. (2011) 'Study protocol: The behaviour and pain in dementia study (BePAID)', BMC Geriatrics, 11(1), 61.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study

- ☐ Database analysis
- ☐ Epidemiology
- ☑ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To develop a palliative care intervention for people with dementia in residential care homes to aid care home staff identify, screen for and monitor palliative care problems and communicate these to healthcare staff.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

To establish the measurement properties of the intervention in order to determine whether it aids care home staff accurately detect palliative care need.

To understand how clinically useful the intervention is including its feasibility for use in routine practice, its interpretability, and how acceptable it is to staff and family members.

To gain an understanding of how the intervention works in practice, in particular, what elements of practice are changed as a result of the intervention.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

WHY IS PALLIATIVE CARE IMPORTANT FOR PEOPLE WITH DEMENTIA?

The predicted prevalence of dementia in the UK is set to double to 1.4 million in the next 30 years (Knapp et al. 2007). This has led to a drive in the way that services for dementia are delivered and funded to ensure improved quality of care and quality of life for people with dementia, and more cost-effective service provision (Department of Health 2009).

Dementia is characterised by progressive decline in cognition resulting in increasing dependence in all areas of functioning. In the advanced stages, people with dementia are almost completely dependent on help in all areas of personal care (Reisberg et al. 1982). There is evidence that people with dementia may experience symptoms such as pain, low mood, constipation, appetite disturbance, confusion, breathlessness and pressure ulcers (McCarthy et al. 1997, Mitchell et al. 2004, Mitchell et al. 2009).

There is growing recognition that palliative care, with its goal of improving quality of life and symptom management, can be of benefit to people with dementia, yet access to palliative care for this population group is limited (Moriarty et al. 2012). As a result, people with dementia continue to have poorly-managed symptoms. They may also be subjected to burdensome interventions to prolong life, including avoidable hospital admissions, which are not beneficial in terms of care and not in keeping with the goals of comfort (Moriarty et al. 2012, Morrison and Siu 2000).

One barrier to accessing palliative care is the difficulties in identifying symptoms and problems in people with dementia, many of whom have significant communication problems (Aminoff et al. 2004). There is also little high-quality research into palliative care interventions for people with dementia, particularly in the UK (Goodman et al. 2010, Sampson et al. 2005). There is therefore a pressing need to develop palliative care interventions that enable people with dementia to access specialist palliative care, reduce unnecessary hospital admissions, and enable prompt treatment of distressing symptoms (Goodman et al. 2010, Moriarty et al. 2012, Mitchell et al. 2012).

WHY IS RESEARCH IN RESIDENTIAL CARE HOMES IMPORTANT?

Dementia is the most frequently cited disorder associated with care home admission and the majority of people admitted to care homes have some cognitive impairment (Bebbington et al. 2001).

The term care home refers to residential settings which provide long-term accommodation for people requiring care (National Care Home Research and Development Forum 2007). Care homes for the elderly are divided into two types: those providing personal care only (residential) and those that provide personal care and nursing (nursing care homes) (Luff et al. 2011). While nursing care homes have on-site nursing staff, residential care homes are not required to have qualified nursing staff and are therefore dependent on NHS primary and community services (Luff et al. 2011). Residential care home staff, who may not have had clinical training, are therefore required to identify palliative care need in the people they care for despite the complexities and challenges this poses. Additionally, care home staff need to be able to communicate these needs to healthcare staff in order to access healthcare for the residents they care for.

There is evidence that barriers exist in the way that social care and healthcare work together (Davies et al. 2011, Gage et al. 2012), yet good partnership working in necessary for improved healthcare access for care home residents (Owen et al. 2008). Facilitators of integrated working include shared assessment and care frameworks and shared documentation (Davies et al. 2011). An intervention that can aid care home staff, the majority of whom will not have clinical training, identify palliative care need in this population is required. Additionally, this intervention should aid integrated working between care home staff and healthcare staff in order for it to have effect on patient care.

WHY DEVELOP AN OUTCOME MEASURE AS AN INTERVENTION?

Measures can be used both to evaluate care and used clinically to provide care, and both are important (Evans et al. 2013, Moriarty et al. 2012). Higginson and Carr (2001) suggest that quality of life outcome measures used in practice can aid identification and prioritisation of problems, facilitate communication between patients and healthcare professionals, screen for problems, aid shared decision making and monitor response to treatments. While it is recognised that this refers to patient-reported outcome measures, it is argued that many of these principles can be applied to proxy-reported outcome measures. This study proposes that implementing outcome measures to be completed by care home staff, and providing clear signs and guidelines for completing them, will aid care home staff identify and screen for problems, and communicate problems to healthcare professionals. It is proposed that it may also facilitate shared decision-making between care home staff and healthcare staff and monitor response to treatment.

WHAT IS THE INTERVENTION?

The proposed intervention will be an adaption of the well-established, valid and reliable (for other conditions) Palliative care Outcome Scale (POS) (Hearn and Higginson 1999) for use with people with dementia (POS-Dem). POS-Dem will be designed with clear identification signs and guidelines to aid care home staff identify palliative care problems in residents with dementia. In addition, it is proposed that POS-Dem, through the use of shared assessment frameworks and documentation, will facilitate communication and joint-working between social and healthcare thereby improving access to healthcare for residents with dementia. It is proposed that through these processes, this intervention will reduce unnecessary and burdensome interventions, while improving symptom management, thus improving quality of life.

REFERENCES:

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', Archives of Gerontology and Geriatrics, 38(2), 123-30.

Bebbington, A., Darton, R. and Netten, A. (2001) Care Homes for Older people: Volume 2 admissions, needs and outcomes. The 1995/96 National Longitudinal Survey of Publicly-Funded Admissions, Personal Social Services Research Unit, University of Kent.

Davies, S., Goodman, C., Bunn, F., Victor, C., Dickinson, A., Iliffe, S., Gage, H., Martin, W. and Froggatt, K. (2011) 'A systematic review of integrated working between care homes and health care services', BMC Health Services Research, 11(1), 320.

Department of Health (2009) Living well with dementia: a national dementia strategy, Crown Copyright.

Evans, C. J., Benalia, H., Preston, N. J., Grande, G., Gysels, M., Short, V., Daveson, B. A., Bausewein, C., Todd, C. and Higginson, I. J. (2013) 'The selection and use of outcome measures in palliative and end-of-life care research: the MORECare international consensus workshop', Journal of Pain and Symptom Management.

Gage, H., Dickinson, A., Victor, C., Williams, P., Cheynel, J., Davies, S. L., Iliffe, S., Froggatt, K., Martin, W. and Goodman, C. (2012) 'Integrated working between residential care homes and primary care: a survey of care homes in England',

BMC Geriatrics, 12(1), 71.

Goodman, C., Evans, C., Wilcock, J., Froggatt, K., Drennan, V., Sampson, E., Blanchard, M., Bissett, M. and Iliffe, S. (2010) 'End of life care for community dwelling older people with dementia: an integrated review', International Journal of Geriatric Psychiatry, 25(4), 329-37.

Hearn, J. and Higginson, I. (1999) 'Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group', Quality in Health Care, 8(4), 219-227.

Higginson, I. J. and Carr, A. J. (2001) 'Using quality of life measures in the clinical setting', BMJ, 322(7297), 1297-1300.

Knapp, M., Prince, M., Albanese, E., Banerjee, S., Dhanasiri, S., Fernandez, J. L., Ferri, C., McCrone, P., Snell, T. and Stewart, R. (2007) Dementia UK: The full report., London: Alzheimer's Society.

Luff, R., Ferreira, Z. and Meyer, J. (2011) Care homes, London: NIHR School for Social Care Research.

McCarthy, M., Addington-Hall, J. and Altmann, D. (1997) 'The experience of dying with dementia: a retrospective study', International Journal of Geriatric Psychiatry, 12(3), 404-9.

Mitchell, S. L., Black, B. S., Ersek, M., Hanson, L. C., Miller, S. C., Sachs, G. A., Teno, J. M. and Morrison, R. S. (2012) 'Advanced dementia: state of the art and priorities for the next decade', Annals of Internal Medicine, 156(1 Pt 1), 45-51.

Mitchell, S. L., Kiely, D. K. and Hamel, M. B. (2004) 'Dying with advanced dementia in the nursing home', Archives of Internal Medicine, 164(3), 321-6.

Mitchell, S. L., Teno, J. M., Kiely, D. K., Shaffer, M. L., Jones, R. N., Prigerson, H. G., Volicer, L., Givens, J. L. and Hamel, M. B. (2009) 'The clinical course of advanced dementia', New England Journal of Medicine, 361(16), 1529-38.

Moriarty, J., Rutter, D., Ross, P. D. S. and Holmes, P. (2012) End of life for people with dementia living in care homes, London: Social Care Institute for Excellence.

Morrison, R. S. and Siu, A. L. (2000) 'Survival in end-stage dementia following acute illness', JAMA: the journal of the American Medical Association, 284(1), 47-52.

National Care Home Research and Development Forum (2007) My Home Life - quality of life in care homes: a review of the literature, London: Help the Aged.

Owen, T., Meyer, J., Bentley, J., Heath, H. and Goodman, C. (2008) 'Better partnership between care homes and the NHS: Findings from the My Home Life programme', Journal of Care Services Management, 3(1), 96-106.

Reisberg, B., Ferris, S. H., de Leon, M. J. and Crook, T. (1982) 'The Global Deterioration Scale for assessment of primary degenerative dementia', The American journal of psychiatry, 139(9), 1136-1139.

Sampson, E. L., Ritchie, C. W., Lai, R., Raven, P. W. and Blanchard, M. R. (2005) 'A systematic review of the scientific evidence for the efficacy of a palliative care approach in advanced dementia', International Psychogeriatrics, 17(1), 31-40.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

PARTICIPATORY APPROACH:

This study will draw upon principles of the participatory approach. The participatory approach is one that includes participatory engagement and collaborative working using the values and principles of: equity (all people have equal worth), engagement (all people have the opportunity to be involved), mutual learning (everyone participating can learn from each other), and honesty (recognising learning opportunities even when things have not gone according to plan) (Froggatt et al. 2009).

Research into care homes has previously been criticised for not taking the care home culture into consideration and there is little understanding of how knowledge from research translates into practice (Froggatt et al. 2009). Indeed, in

reason for these focus groups being multidisciplinary will be to gain consensus amongst all professionals as to what the important components of POS-Dem are, what aspects of POS-Dem will aid the clinical usefulness of POS-Dem, and how POS-Dem can best be used to aid communication. Topic guides will be used to initiate discussion. These will be developed based on the narrative synthesis and systematic review in phase one. Additionally, case vignettes will also be given to the participants in the focus group in order to gain an understanding of how they may use POS-Dem in practice. Again, it is proposed that three focus groups, one at each home, will be sufficient to obtain theoretical saturation but if required, more focus groups will be carried out until saturation is achieved or all available resources have been exhausted.

Focus groups with paid professionals will be carried out at a time and place most convenient to the majority of participants. Given the fact that all the paid professionals will be likely to have many clinical commitments, the mix of disciplines in each focus group will not be specified.

Semi-structured interviews:
While focus groups are the preferred method of obtaining these data, it is likely that not all eligible paid professional participants will be able to attend the focus groups. Should, theoretical saturation not be obtained and more participants required who do not have the flexibility to attend focus groups, then semi-structured interviews will be carried out with these participants. These interviews will use the same topic guides and case vignettes as the focus groups.

All focus groups and interviews will be recorded, transcribed and analysed. In order to aid analysis of the focus groups, participants will be requested that their names are used in the recordings so that individual contributions and professions can be identified. When the recordings are transcribed, names will be removed and identification codes used instead.

Cognitive interviews:
Once the focus groups and semi-structured interviews have been analysed and changes made to POS-Dem, cognitive interviews will be carried out in order to make sure that they are easy to understand. Five to 10 care home staff will be purposively sampled to complete the measure and to 'think out loud' while they do so. In addition, the technique of 'verbal probing' will be used in order to test how well the questions are understood, processed and responded to. This technique is known as 'cognitive interviewing' (Willis 2005).

The results of the focus groups will inform what grade of care home staff will be completing POS-Dem and as a result, will inform which care home staff will be recruited to take part in cognitive interviewing. These staff will be purposively sampled in order to gain a range of participants with different demographics (including level of training, experience, and English as a second language).

Output of phase 2:
At the end of phase two, a final version of POS-Dem will have been developed with established content validity. It will have been developed to be acceptable and feasible to use in routine practice.

PHASE 3: PILOT STUDY (see chart for details of data collection points)

This phase of the study will be a four month implementation of the study in order to:
- Test some of the measurement properties of POS-Dem
- Establish how acceptable it is to unpaid carers and paid professionals
- Establish how useful it is for use in routine practice
- Determine how it works in practice (its underlying mechanisms of action)
- Establish the interpretability of POS-Dem

It will be at this stage that residents will be recruited to participate in the study. Resident participation will involve having information (such as medication changes, care plan reviews and hospital admissions) extracted from their notes for the month preceding the POS-Dem being implemented and for the final month of the intervention. These process measures will be informed by both the literature and the focus groups with paid professionals. This is because paid professionals will be asked how they believe implementing POS-Dem may change practice. At the point at which POS-Dem is implemented (T0) and at the end of the implementation (T4), two outcome measures with established validity and reliability will be used with care home staff for each resident. These outcome measures will be chosen on the basis of the narrative synthesis in phase 1 but may include:

- Support Team Assessment Schedule (STAS) (Higginson and McCarthy 1993) or equivalent
- Mini Suffering State Examination (MSSE) (Aminoff et al. 2004) or equivalent

Five days after T0, POS-Dem will be repeated in order to establish test-retest reliability. Finally, resident participants

will receive the intervention for the period of four months. During this time, POS-Dem will be completed for each participant by a care home staff member in order to identify palliative care need. It is proposed that this will be on a monthly basis but this will be determined at the time of the focus groups in phase two. In order to gain an understanding of the interpretability of POS-Dem and how it may change practice, participant observation will also be carried out. In each care home, in the first and third month of the intervention period, a consultation between care home staff and either a GP or district nurse regarding resident particpants will be observed.

Focus groups with unpaid carers will be carried out at the end of the four months in order to determine how acceptable the intervention has been for this group. The same principles described in phase 2 will be used again although different topic guides will be used. Topic guides will be developed based on data collected and analysed in phases one and two.

Focus groups will be carried out with paid professionals at the end of the four months to establish how acceptable and useful the intervention has been for practice. The same principles described in phase 2 will be used again although different topic guides will be used. Topic guides will be developed based on data collected and analysed in phases one and two. They may also be informed by the data from participant observations.

REFERENCES:

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', Archives of Gerontology and Geriatrics, 38(2), 123-30.

Antunes, B., Harding, R., Higginson, I. J. and EUROIMPACT, o. b. o. (2013) 'Implementing patient-reported outcome measures in palliative care clinical practice: A systematic review of facilitators and barriers', Palliative Medicine.

Bausewein, C., Le Grice, C., Simon, S. and Higginson, I. (2011) 'The use of two common palliative outcome measures in clinical care and research: A systematic review of POS and STAS', Palliative Medicine, 25(4), 304-313.

Brandt, H. E., Deliens, L., van der Steen, J. T., Ooms, M. E., Ribbe, M. W. and van der Wal, G. (2005) 'The last days of life of nursing home patients with and without dementia assessed with the Palliative care Outcome Scale', Palliative Medicine, 19(4), 334-42.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M. (2008) 'Developing and evaluating complex interventions: the new Medical Research Council guidance', BMJ, 337(sep29_1), a1655-a1655.

Evans, C. J., Harding, R. and Higginson, I. J. (2013) "Best practice'in developing and evaluating palliative and end-of-life care services: A meta-synthesis of research methods for the MORECare project', Palliative Medicine.

Froggatt, K., Davies, S. and Meyer, J. (2009) 'Research and development in care homes: setting the scene' in Froggatt, K., Davies, S. and J., M., eds., Understanding Care Homes: A Research and Development Perspective, London: Jessica Kingsley Publishers, 9-22.

Greenhalgh, J. (2009) 'The applications of PROs in clinical practice: what are they, do they work, and why?', Quality of Life Research, 18(1), 115-123.

Greenhalgh, J., Long, A. F. and Flynn, R. (2005) 'The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory?', Social Science and Medicine, 60(4), 833-843.

Greenhalgh, J. and Meadows, K. (1999) 'The effectiveness of the use of patient-based measures of health in routine practice in improving the process and outcomes of patient care: a literature review', Journal of Evaluation in Clinical Practice, 5(4), 401-416.

Gysels, M. H., Evans, C. and Higginson, I. J. (2012) 'Patient, caregiver, health professional and researcher views and experiences of participating in research at the end of life: a critical interpretive synthesis of the literature', BMC Medical Research Methodology, 12(1), 123.

Higginson, I. J. and McCarthy, M. (1993) 'Validity of the support team assessment schedule: do staffs' ratings reflect those made by patients or their families?', Palliative Medicine, 7(3), 219-228.

Medical Research Council (2000) 'A framework for development and evaluation of RCTs for complex interventions to improve health', available: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC0033 72 [accessed 19/12/2012].

Parker, D. and Hodgkinson, B. (2011) 'A comparison of palliative care outcome measures used to assess the quality of palliative care provided in long-term care facilities: a systematic review', Palliative Medicine, 25(1), 5-20.

Snyder, C. F., Aaronson, N. K., Choucair, A. K., Elliott, T. E., Greenhalgh, J., Halyard, M. Y., Hess, R., Miller, D. M., Reeve, B. B. and Santana, M. (2012) 'Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations', Quality of Life Research, 21(8), 1305-1314.

Valderas, J., Kotzeva, A., Espallargues, M., Guyatt, G., Ferrans, C., Halyard, M., Revicki, D., Symonds, T., Parada, A. and Alonso, J. (2008) 'The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature', Quality of Life Research, 17(2), 179-193.

van Soest-Poortvliet, M. C., van der Steen, J. T., Zimmerman, S., Cohen, L. W., Klapwijk, M. S., Bezemer, M., Achterberg, W. P., Knol, D. L., Ribbe, M. W. and de Vet, H. C. (2012a) 'Psychometric properties of instruments to measure the quality of end-of-life care and dying for long-term care residents with dementia', Quality of Life Research, 21(4), 671-84.

van Soest-Poortvliet, M. C., van der Steen, J. T., Zimmerman, S., Cohen, L. W., Munn, J., Achterberg, W. P., Ribbe, M. W. and de Vet, H. C. (2011) 'Measuring the quality of dying and quality of care when dying in long-term care settings: a qualitative content analysis of available instruments', Journal of Pain and Symptom Management, 42(6), 852-63.

van Soest-Poortvliet, M. C., van der Steen, J. T., Zimmerman, S., Cohen, L. W., Reed, D., Achterberg, W. P., Ribbe, M. W. and de Vet, H. C. (2012b) 'Selecting the Best Instruments to Measure Quality of End-of-Life Care and Quality of Dying in Long Term Care', Journal of the American Medical Directors Association.

Volicer, L., Hurley, A. C. and Blasi, Z. V. (2001) 'Scales for evaluation of End-of-Life Care in Dementia', Alzheimer Disease and Associated Disorders, 15(4), 194-200.

Willis, G. B. (2005) Cognitive interviewing: A tool for improving questionnaire design, SAGE Publications, Incorporated.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
The study has been presented at an older adult mental health service user and carer group. This group has advised on the study design and intervention and has agreed to being consulted throughout the duration of the project.

In addition, a layperson who has been a carer for a family member with dementia in a care home, has been consulted and has agreed to be involved and consulted for the duration of the study. The protocol has been shared with this layperson and she has also read, commented on and revised the particpant information sheets, posters and consent forms for residents and unpaid carers.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

RESIDENT PARTICIPANTS:

- Permanent resident in the care home
- Formal diagnosis of dementia (any stage) OR
- Cognitive impairment of level 4 to 7 on the Global Deterioration Scale based on care home staff reports and interview by a member of the research team

UNPAID CARERS:

- Capacity to consent for themselves
- Any family or friend of a resident in the care home who considers themselves a carer of a resident with cognitive impairment

CARE HOME STAFF:

- All care home staff of different grades including qualified nursing staff and support (domestic) staff
- Depending on outcome of focus groups, cognitive interviews may only include care home staff who complete resident records

GPs:

- All GPs responsible for routine medical care of residents in the participating care homes

DISTRICT NURSES:

- All district nurses of all grades who work with residential care homes

REFERENCE:

Reisberg, B., Ferris, S. H., de Leon, M. J. and Crook, T. (1982) 'The Global Deterioration Scale for assessment of primary degenerative dementia', The American journal of psychiatry, 139(9), 1136-1139

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

RESIDENT PARTICIPANTS:

- Receiving specialist palliative care

UNPAID CARERS:

- Under the age of 18

GPs AND CARE HOME STAFF:

- none

DISTRICT NURSES:

- Specialist nures such as palliative care nurses or community mental health nurses

REFERENCE:

Reisberg, B., Ferris, S. H., de Leon, M. J. and Crook, T. (1982) 'The Global Deterioration Scale for assessment of primary degenerative dementia', The American journal of psychiatry, 139(9), 1136-1139

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
RESIDENTS AND UNPAID CARERS: VOLUNTARY COFFEE MORNING TO PROVIDE INFORMATION ON STUDY	2	0	120-180 MINUTES	The doctoral student and research team working under Professor Irene Higginson Venue: the care home
RESIDENT: SEEKING CONSENT AND ADVICE FROM A CONSULTEE	1	0	30-60 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home where the resident lives
RESIDENT AND CARE HOME STAFF: MINI SUFFERING STATE EXAMINATION (MSSE) OR EQUIVALENT COMPLETED FOR RESIDENT BY CARE HOME STAFF	2	0	10-20 MINUTES	The doctoral student, or any researcher working under Professor Irene Higginson Venue: care home where the resident lives
RESIDENT AND CARE HOME STAFF: SUPPORT TEAM ASSESSMENT SCHEDULE (STAS) OR EQUIVALENT COMPLETED FOR RESIDENT BY CARE HOME STAFF	2	0	10-20 MINUTES	The doctoral student or any researcher working under Professor Irene Higginson Venue: care home where the resident lives
RESIDENT AND CARE HOME STAFF: POS-DEM	6	0	10-15 MINUTES	This will be the intervention that is established into routine care for four months. As such, apart from at the first two and last time points, this will be carried out by care home staff in the care home in the absence of research staff
CARE HOME STAFF: SEEKING CONSENT (NOTE: DIFFERENT CARE HOME STAFF MAY BE INVOLVED AT DIFFERENT PHASES OF THE STUDY. THE FOLLOWING IS THE MAXIMUM THAT ONE CARE HOME STAFF MAY BE INVOLVED).	5	0	10-15 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home
CARE HOME STAFF: FOCUS GROUPS AND/OR INTERVIEWS (NOTE:DIFFERENT CARE HOME STAFF MAY BE INVOLVED AT DIFFERENT PHASES OF THE STUDY. THE FOLLOWING IS THE MAXIMUM THAT ONE STAFF MEMBER MAY BE INVOLVED)	3	0	60-120 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: most convenient venue for the majority of participants
UNPAID CARERS: CONSENT (NOTE: NOT ALL UNPAID CARERS WILL BE INVOLVED IN BOTH PHASES. THE FOLLOWING IS THE MAXIMUM THAT ONE UNPAID CARER MAY BE INVOLVED).	2	0	13-30 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home or other place of convenience for participants
UNPAID CARERS: FOCUS GROUPS (NOTE: NOT ALL UNPAID CARERS WILL BE INVOLVED IN BOTH PHASES. THE	2	0	60-120 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home or other place of convenience for participants

FOLLOWING IS THE MAXIMUM THAT ONE UNPAID CARER MAY BE INVOLVED).			
DISTRICT NURSES: CONSENT (NOTE: NOT ALL DISTRICT NURSES WILL BE INVOVLED IN BOTH PHASES. THE FOLLOWING IS THE MAXIMUM THAT ONE DISTRICT NURSE WILL BE INVOLVED).	4 0	10-20 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home or other place of convenience for participants
DISTRICT NURSES: FOCUS GROUPS OR INTERVIEWS: (NOTE: NOT ALL DISTRICT NURSES WILL BE INVOVLED IN BOTH PHASES. THE FOLLOWING IS THE MAXIMUM THAT ONE DISTRICT NURSE WILL BE INVOLVED).	2 0	60-120 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home or other place of convenience for participants
GENERAL PRACTIONERS: CONSENT (NOTE:NOT ALL GPs WILL BE INVOLVED FOR BOTH PHASES. THE FOLLOWING IS THE MAXIMUM THAT ONE GP MAY BE INVOLVED).	4 0	10-20 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home or other place of convenience for participants
GENERAL PRACTIONERS: FOCUS GROUPS OR INTERVIEWS (NOTE:NOT ALL GPs WILL BE INVOLVED FOR BOTH PHASES. THE FOLLOWING IS THE MAXIMUM THAT ONE GP MAY BE INVOLVED).	2 0	60-120 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home or other place of convenience for participants
CARE HOME STAFF, GPs AND DISTRICT NURSES: PARTICIPANT OBSERVATION OF CONSULTATIONS (NOTE: NOT ALL OF THESE PARTICIPANTS WILL BE INVOLVED FOR ALL OBSERVATIONS. THE FOLLOWING IS THE MAXIMUM FOR ONE)	2	60-120 MINUTES	The doctoral student or any other researcher working under Professor Irene Higginson Venue: care home

A21. How long do you expect each participant to be in the study in total?

RESIDENT PARTICIPANTS:
Resident particpants will be in the study for 4-5 months

UNPAID CARERS:
Phase 2 - focus group <120 minutes
Phase 3 - focus group <120 minutes
(recruited separately)

CARE HOME STAFF:
Phase 2 - focus group and/or cognitive interview <120 minutes
Phase 3 - 4-5 months
Phase 3 - two participant observations with GP/district nurse consultation <120 minutes
Phase 3 - focus group <120 minutes
(recruited separately at each phase)

GPs AND DISTRICT NURSES:
Phase 2 - focus group <120 minutes
Phase 3 - 4-5 months using intervention as part of routine practice
Phase 3 - two participant observations of consultation with care home staff <120 minutes
Phase 3 - focus group <120 minutes
(recruited separately at each phase)

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

RESIDENT PARTICIPANTS:

- Taking part in the study will involve reading and recording resident records which involves personal and medical information. In order to protect confidentiality, this information will be anonymised and will only be identifiable by a identity code stored separately from the data.

- As POS-Dem has not yet been validated there is a small risk that problems may be correctly or incorrectly identified. This may need to an increase in investigations. POS-Dem, however, will not be designed to and will not replace clinical judgement. All investigations will therefore be a result of clinicians' judgement. POS-Dem may help alert clinicians to possible problems.

- All resident participants can withdraw from the study at any time and their consultees can withdraw residents from the study without providing explanation. This will be made explicit in the information leaflets.

UNPAID CARERS:

- Participating in focus groups regarding the care of family or friends may explore sensitive topics and be distressing. Participants need not answer any questions and may withdraw from the study at any time. Where necessary, a distress protocol will be followed.

- All focus groups will be recorded. In addition, participants will be asked whether their names can be used on the recording in order to aid analysis. Once the focus groups have been transcribed, pseudonymised codes will be used which will be stored separately from the transcripts.

- Participating in focus groups is time consuming. Times and venues will be arranged according to the preferences of the majority of participants. Light meals or refreshments will be provided to fit into time schedules.

- While the research team will adhere to data protection in order to ensure confidentiality, this cannot be guaranteed as other research participants may share what has been said in the focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality.

PAID PROFESSIONALS:

- Focus groups and interviews with paid professionals will be recorded and, in the case of focus groups, participants will be asked whether their names can be used on the recordings. Once the focus groups have been transcribed, pseudonymised codes will be used which will be stored separately from the transcripts.

- Paid professionals are busy and participating in this study will add to the burden. Times and venues will be arranged around the preferences of the majority of participants. Where participants are not able to attend focus groups, semi-structured interviews will be offered at a time and location convenient to the participants. In order to fit into busy time schedules refreshments or light meals will be provided.

- While the research team will adhere to data protection in order to ensure confidentiality, this cannot be guaranteed as other research participants may share what has been said in the focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◉ Yes ○ No

If Yes, please give details of procedures in place to deal with these issues:

FOCUS GROUPS WITH UNPAID CARERS:

Participating in focus groups regarding the care of family or friends may explore sensitive topics and be distressing. Participants will be given the choice not to answer any questions. They will be advised in the information leaflets and verbally that they can leave the focus group and/or withdaw from the study at any time.

The doctoral student is an experienced mental health clinician and other researchers assisting in the focus groups

will have experience of interviewing in senstive areas and have relevant clinical qualifications. All staff carrying out the focus groups are supervised by senior researchers and clinicians, and the department has extensive experience in research in palliative care. Any risk, includng suicidal risk, will be urgently escalated to the CI. A distress protocol has been developed that will be followed in the event that distress is caused by the study.

UNPAID CARERS AND PAID PROFESSIONALS FOCUS GROUPS AND INTERVIEWS:

It is possible that unsafe practice with the potential of causing harm to residents may be revealed. All concerns will be escalated to the CI. Paid professionals and unpaid carers will be advised that all information will be kept confidential unless it is revealed that vulnerable adults are at risk. In the event of safeguarding concerns being revealed, [redacted] council safeguarding vulnerable adults team will be contacted and concerns reported.

A24. What is the potential for benefit to research participants?

RESIDENTS:

This intervention aims to improve the detection of palliative care problems, enable prompt treatment of symptoms while reducing burdensome interventions and avoidable admissions. The effectiveness, of this intervention has not yet been established.

UNPAID CARERS:

There is a growing body of evidence to suggest that family members of palliative care recipients experience benefit from participating in research (Gysels et al. 2012, Gysels et al. 2008). Additionally, Gysels et al. (2012)propose that the more collaborative approach of participatory approach can result in a sense of empowerment for participants.

PAID PROFESSIONALS:

Paid professionals will gain the opportunity to contribute to the development of an intervention that can be used with the residents/patients that they work with.

REFERENCES:

Gysels, M., Shipman, C. and Higginson, I. J. (2008) 'Is the qualitative research interview an acceptable medium for research with palliative care patients and carers?', BMC Medical Ethics, 9(1), 7.

Gysels, M. H., Evans, C. and Higginson, I. J. (2012) 'Patient, caregiver, health professional and researcher views and experiences of participating in research at the end of life: a critical interpretive synthesis of the literature', BMC Medical Research Methodology, 12(1), 123.

A26. What are the potential risks for the researchers themselves? *(if any)*

Exploring senstive emotional areas or dealing with distressed participants can lead to distress within the research team. The research will be conducted with the Department of Palliative Care, Policy and Rehabilation which is a team with extensive experience in conducting research in palliative and end-of-life care. There is informal support within the department and the all researchers receive supervision.

We will offer participants the option of completing focus groups or interviews in a place and time that is most convenient to them. This will require researchers visiting participants in the community (most likely care homes). We will follow the department's lone working policy as follows: All those working off-site in this way are required to complete a log showing where they are going to conduct an interview. All researchers will be paired with a partner to ensure that a named indvidual knows their whereabouts at all times.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

RESIDENT PARTICIPANTS:

As many of the resident participants will lack capacity to consent, recruiting resident participants will involve identifying them and potential consultees. As such, prior to any recruitment, posters will be displayed with details of the project and contact details of the doctoral student. A coffee morning in each participating care home will be advertised on the poster. This will give residents, friends and family the opportunity to ask more questions about the research. Additionally, it will give residents and unpaid carers the opportunity to request that they or their family member or friend is not approached if they so wish.

The doctoral student and/or research team will then spend time in the care home with the manager or senior member of staff who will be asked to identify eligible residents and introduce them to the research team member. If the resident is in agreement, the researcher will meet and discuss the project with the aid of a single side information sheet. This will be left with the resident along with a more detailed information sheet for family members. If the resident has capacity, the researcher will return to gain consent. If the resident consents or if the resident does not have capacity, the researcher will commence the process of gaining advice from a consultee. In order to maintain confidentiality, the care home staff will be asked to identify personal consultees and to gain consent for the research team to contact them.

UNPAID CARERS:

Unpaid carers will be recruited through poster advertising and coffee mornings as described. Additionally, care home staff will be asked to identify eligible unpaid carers who have not attended the coffee morning and gain consent for them to be contacted by the research team.

PAID PROFESSIONALS:

Care homes, district nurse teams and GPs will be identified prior to the study commences. At each time point that they participate, they will be approached directly for participation.

At the time of recruitment demographic data on all participants will be collected. For residents this will be from the care home notes and all other participants will be asked directly to provide demographic details.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
Consent or advice from consultees will be obtained prior to any personal identifiable information being accessed by the research team.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Posters will be displayed in the care homes to advertise the project and coffee mornings.

A29. How and by whom will potential participants first be approached?

RESIDENT PARTICIPANTS:

Resident participants will be approached first by the care home staff who will introduce the a member of the research team to the resident.

UNPAID CARERS:

Unpaid carers will be invited through posters to attend a coffee morning or to contact the research team directly. Additionally, care home staff will be asked to approach eligible unpaid carers directly to ascertain whether they are prepared to be contacted by the research team.

PAID PROFESSIONALS:

Once care homes, GP surgeries and district nurse teams have been identified and partication agreed, individual participants will be approached directly by the research team. In the case of care homes and district nurses, managers will be approached initially. GPs will be approached directly to discuss potential participation.

A30-1. Will you obtain informed consent from or on behalf of research participants?

(●) Yes ( ) No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

RESIDENT PARTICIPANTS:

A member of the research team will meet with eligible participants and discuss the study with the aid of a single-sided information sheet. Should the participants have the capacity to comprehend this, then the information sheet and a more detailed information leaflet (for the benefit of family members or friends who may visit) will be left with them. A member of the research team will return after a week (or more if requested) to gain written consent. It will be reiterated at both points to the potential participant that their participation will NOT affect their management in any way.

Once someone has decided that they would like to participate, they will be required to fully comprehend the risks, benefits and burdens of their taking part, and give written informed consent to do so. As it is expected that residents may lose capacity during the research period, or capacity may fluctuate, advice from consultees will also be obtained. Capacity will be monitored through discussion with the care home staff but residents will not be withdrawn from the study should they lose capacity.

UNPAID CARERS:

At the time of the coffee morning, information about the study will be presented to unpaid carers. At this time, written information leaflets will be provided and members of the research team will be available to answer any questions.

For those family members who contact the research team directly or who have consented (through care home staff) for the research team to contact them, they will all be offered the option of either having the information leaflets posted to them, or to meet with a member of the research team face-to-face to discuss the project and what participation would entail. All unpaid carers who participate in the focus groups will be met by a member of the research team prior to the focus group commencing. They will be required to fully comprehend the risks, benefits and burdens of taking part, and give written informed consent to do so.

PAID PROFESSIONALS:

Paid professionals will be given written information leaflets prior to participating in any focus groups or interviews. This will be carried out at the the same time as the focus groups or interviews so as to minimise the professionals' time required. They will then be aksked to give written informed consent prior to participating.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

RESIDENTS, PERSONAL CONSULTEES (ON BEHALF OF RESIDENTS WITHOUT CAPACITY) AND UNPAID CARERS:

A mimimum of 24 hours will be given to these particpant groups. For residents who have capacity we will give them a leaflet and leave this with them for at least one week, or longer if they require, to provide them the opportunity for family to read the leaflet and discuss this with residents.

Unpaid carers will be provided with information about the study and asked to be provide informed written consent at the time of the focus groups. This will be a minimum of 24 hours but more likely to be a period of weeks.

PAID PROFESSIONALS:

In order to account for the busy time schedules of the paid professionals, they will be given information sheets at the same time as providing informed written consent. All potential paid professionals, however, will have been provided information about the study and its purposes at the time their teams/organisations became involved in the study. At this time and at the time of getting written consent, these participants will be given the opportunity to ask questions.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

RESIDENT PARTICIPANTS:

Due to limited resources it will not be possible to use interpreters and translators and those residents who are unable to communicate in English will therefore have to be excluded. Large print leaflets will be provided for people with visual impairment and the use of visual aids will be used with those who have hearing difficulties.

ALL OTHER PARTICPANTS:

As all participants, other than residents, will be asked to participate in focus groups and interviews, people who do not speak English will be excluded from the study. Such people will not be able to particpate in focus groups, where we hope that the discussion will spark a better flow of ideas.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

◉ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

As all resident particpants will have dementia or cognitive impairment, it is likely that some will have fluctuating capacity or

lose capacity over the period of the study. As such, at the time of gaining consent from resident participants, advice from a personal or professional consultee will also be obtained (Gysels et al. 2013). Should a resident lose capacity during the time of the study, advice from a consultee as described by the Mental Capacity Act (2005) would have been obtained.

REFERENCES:

Gysels, M., Evans, C. J., Lewis, P., Speck, P., Benalia, H., Preston, N. J., Grande, G. E., Short, V., Owen-Jones, E. and Todd, C. J. (2013) 'MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research', Palliative Medicine.

Mental Capacity Act (2005) Chapter 9, London: HMSO.

Please complete Part B, Section 6, giving further information about arrangements for including adults unable to consent for themselves.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files including X-rays
  - ☐ NHS computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
All electronic data will be stored on encrypted external hard drives or encrypted memory data sticks.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All participants who choose to participate in this study will be assured that steps will be taken to anonymise their identity.

All personal data will be stored by the research team (including audio recordings) in secure locked cabinets at the Department of Palliative Care, Policy and Rehabilitation, King's College London in accordance with the Data Protection Act and the Department Data Management Guidelines. Access will be restricted and controlled.

Researchers will anonymise and code data as early as possible and to the full extent possible within the needs of the study, only essential personal information will be held. These codes will be stored in a research "code book" and stored elsewhere should it be required for research analysis or presentation of findings at a later date.

To secure access to personal information, the "code book" containg identifiable information and a unique identifier (code) assigned to individual data subjects will be maintained. This means, for example, that codes will be assigned to participants before qualitative focus groups or interviews are transcribed and quantitative data inputted.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

- Dr Barbara Daveson (Chief Investigator and PhD supervisor)
- Dr Catherine Evans (PhD supervisor)
- Professor Irene Higginson (PhD supervisor)
- Clare Ellis-Smith (doctoral student)
- Any research staff working on the project within the Department of Palliative Care, Policy and Rehabilitation, King's College London. For example, the clinical research nurses employed in the department to assist in NIHR CRN projects.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
All pseudonymised data will be kept for seven years after the study has ended in accordance with the guidelines of the Department of Palliative Care, Policy and Rehabilitation, King's College London. This will allow for validation of results following publication.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes ○ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
There will be provision if required to offer participants out of pocket expenses e.g. for travel reimbursement.

Additionally, refreshments will be provided at care home coffee mornings.

In order to fit into the schedules of all participants, refreshments will also be provided at focus groups.

Certificates of participation will be offered to care homes in order to acknowledge the contibution they have made. All paid professionals will also be offered certificates for the CVs to acknowledge the contribution that they have made.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or

incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ◯ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ◯ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ◯ No

Please give details, or justify if not registering the research.
National Institute of Health Research (NIHR) portfolio database.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
All paid professionals will be informed of the study results, through a summary of the study results and details of publications.

We will not routinely inform resident participants of the findings of the study as many of the patient participants may die or have siginificant cognitive impairment by the end of the study. At the time of consent we will offer residents the option of receiving the findings. If resident participants express a wish to be informed of the study findings we will allow for this. However, we will first ascertain the clinical status of the participants before disseminating results.

As unpaid carers will be carers of residents who both have participated and not particpated in the study, it will not be possible to ascertain the medical status of all the residents who unpaid carers look after without breaching confidentiality. As such, it will not be possible to determine whether they have passed away and it would not be an appropriate time to contact unpaid carers. A more passive approach of dissemination will therefore be provided, where informal carers will be advised that they can obtain the results from the care home. Copies of the summary of the results or details of how to obtain a copy will be left with the care home for this purpose.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi-centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This project was internally peer reviewed within the Department of Palliative Care, Policy and Rehabilitation, King's College London.

The PhD fellowship is part of a peer reviewed external grant award, Project BuildCARE, which requires a PhD on this topic. This project has also been discussed by the Cicely Saunders Institute International Scientific Expert Panel.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☑ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi-centre group
- ☑ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Professor	Irene	Higginson
Department	Department of Palliative Care, Policy and Rehabilitation		
Institution	King's College London, Cicely Saunders Institute		
Work Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
Post Code	SE5 9PJ		
Telephone	02078485516		
Fax	02078485517		
Mobile			
E-mail	irene.higginson@kcl.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

As this is not a traditional RCT, this project does not have a primary outcome measure. The primary aim of the project is as follows:

To develop the Palliative care Outcome Scale for use with people with dementia living in residential care homes.

A58. What are the secondary outcome measures? *(if any)*

To measure the validity and reliability of POS-Dem to determine whether it accurately aids residential care home staff to identify palliative care need for people with dementia.

To understand the acceptability, interpretability, and feasibility of POS-Dem for use in routine care

To gain an understanding of the intervention and how it works in practice including
- process measures e.g. Gold Standards Framemwork Registration, integrated care plans, decisions regarding place of care, medication reviews (including prescriptions of analgesics), and referrals to specialist services. Process measures will be established both from the literature and from focus groups in phase two.
- outcome measures of Symptom Management in Mini Suffering State Examination (MSSE)(Aminoff et al. 2004)or equivalent and Support Team Assessment Schedule (STAS)(Higginson and McCarthy 1993). Outcome measures will be determined based on the phase one literature review.

REFERENCES:

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', Archives of Gerontology and Geriatrics, 38(2), 123-30.

Higginson, I. J. and McCarthy, M. (1993) 'Validity of the support team assessment schedule: do staffs' ratings reflect those made by patients or their families?', Palliative Medicine, 7(3), 219-228.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	165
Total international sample size (including UK):	165
Total in European Economic Area:	165

Further details:
65 residents with dementia

Up to 45 (15 in each care home) unpaid carers with dementia depending on numbers attending focus groups and theoretical saturation

Up to 10 primary healthcare professionals (three to four for each care home) depending on numbers attending focus groups and theoretical saturation

Up to 45 (15 in each care home) care home staff members for focus groups and interviews (depending on size of care home, numbers of staff attending and theoretical saturation)

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Focus groups of size 8-15 to allow for non-attendance will be carried out at both phases of the study. It is anticipated that three focus groups with paid professionals at each phase will be sufficient to achieve theoretical saturation but more will be carried out until theoretical saturation is achieved or all resources have been exhausted. One focus group at each care home will be carried out at each care home setting with unpaid carers of size 8-15 which should be sufficient to achieve theoretical saturation. However, additional focus groups with unpaid carers may be carried out until theoretical saturation is achieved or all resources have been exhausted.

Five to 10 cognitive interviews will be carried out with care home staff (Willis 2005).

The sample size for the pilot study in phase three will include 65 resident participants. The number recommended as a minimum for reliability studies is 50 (de Vet et al. 2011, Terwee et al. 2007) which will be the main quantitative outcome of the study. An additional 30% (n=15) is included in the sample size to account for attrition resulting in a total of 65.

REFERENCES:

de Vet, H. C., Terwee, C. B., Mokkink, L. B. and Knol, D. L. (2011) Measurement in medicine, Cambridge: Cambridge University Press.

Terwee, C. B., Bot, S. D., de Boer, M. R., van der Windt, D. I. A., Knol, D. L., Dekker, J., Bouter, L. M. and de Vet, H. C. (2007) 'Quality criteria were proposed for measurement properties of health status questionnaires', Journal of Clinical Epidemiology, 60(1), 34-42.

Willis, G. B. (2005) Cognitive interviewing: A tool for improving questionnaire design, SAGE Publications, Incorporated.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

FOCUS GROUPS, SEMI-STRUCTURED INTERVIEWS AND COGNITIVE INTERVIEWS:

Qualitative data from focus groups, semi-structured interviews (if carried out), and cognitive interviews will recorded, transcribed and analysed. Deductive content analysis will be carried out with all qualitative data including participant observations. NVivo will be used to help manage and categorise the data. To reduce bias, analysis will be discussed with the doctoral student's supervisors on a regular basis.

QUANTITATIVE DATA ANALYSIS:

Data from the pilot study will be presented as summary statistics to describe the sample and nature of the distribution of scores.

- Construct validity will be determined through Spearman's rho correlation coefficients with POS-Dem and established outcome measures.
- Cronbach's alpha coefficients will be calculated for test-retest reliability between two time points of completing POS-Dem on a subgroup of stable residents. Stable residents will be determined by those residents who have not required any consultations with health practitioners and no medication changes.
- Cronbach's alpha will be used to test internal consistency
- Mean/median scores with standard deviations/interquartile ranges for overall scores and each item for the two outcome measures will be calculated at each time point (before and after). Mean change will be calculated to determine the effect of the intervention on patient symptoms and palliative care need.
- Descriptive statistics for all process measures possibly including numbers of Gold Standards Framework registration, integrated care plan reviews, decisions regarding place of care, medication reviews, and referrals to specialist services (these will be determined in phase 2). These will be presented as medians and interquartile ranges or counts and percentages.
- Mean/median scores with standard deviations/interquartile ranges for overall POS-Dem scores and each item will be calculated for each time point. Mean changes will be calculated for each time point.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Ms	Clare	Ellis-Smith
Post	PhD Training Fellow		
Qualifications	BSc Occupational Therapy MSc		
Employer	King's College London		
Work Address	King's College London, Cicely Saunders Institute Bessemer Road Denmark Hill, London		
Post Code	SE5 9PJ		
Telephone	02078485434		
Fax	02078485517		
Mobile			
Work Email	alexandra.c.ellis-smith@kcl.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Catherine	Evans
Post	Clinical Lecturer		
Qualifications	BSc MSc PhD		
Employer	King's College London		
Work Address	King's College London, Cicely Saunders Institute Bessemer Road Denmark Hill, London		
Post Code	SE5 9PJ		

Telephone	02078485579
Fax	02078485517
Mobile	
Work Email	catherine.evans@kcl.ac.uk

Title	Forename/Initials	Surname
Professor	Irene	Higginson

Post	Head of Department - Palliative Care, Policy and Rehabilitation
Qualifications	BMedSci BMBS FFPHM PhD
Employer	King's College London
Work Address	King's College London, Cicely Saunders Institute Bessemer Road Denmark Hill, London
Post Code	SE5 9PJ
Telephone	02078485516
Fax	02078485517
Mobile	
Work Email	irene.higginson@kcl.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

If Other, please specify:

Commercial status: Non-Commercial

Contact person

Name of organisation	King's College London
Given name	Keith
Family name	Brennan
Address	Room 1.8 Hodgkin Building, Guy's Campus
Town/city	London
Post code	SE1 4UL
Country	UNITED KINGDOM
Telephone	02078486960
Fax	02078486394
E-mail	keith.brennan@kcl.ac.uk

Is the sponsor based outside the UK?
○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☑ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☐ No application for external funding will be made

What type of research project is this?

○ Standalone project
◉ Project that is part of a programme grant
○ Project that is part of a Centre grant
○ Project that is part of a fellowship/ personal award/ research training award
○ Other

Other – please state:

Please give details of funding applications.

Organisation	Cicely Saunders International
Address	Cicely Saunders Institute Bessemer Road Denmark Hill, London
Post Code	SE5 9PJ
Telephone	02078485580
Fax	
Mobile	
Email	brenda.ferns@cicelysaundersinternational.org

Funding Application Status: ◉ Secured ○ In progress

Amount: 2,443,112.00

Duration
Years: 4
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Project BuildCARE funded by Cicely Saunders International

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Zoe	Harris
Organisation	King's College Hospital NHS Foundation Trust		
Address	1st floor Jennie Lee House		
	Love Walk		
	London		
Post Code	SE5 8AD		
Work Email	zoe.harris@gstt.nhs.uk		
Telephone	02032993841		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Comprehensive Local Research Network for this NHS organisation:

To support communication between the REC and R&D contacts for this study, please select the Comprehensive Local Research Network (CLRN) for this NHS organisation. This CLRN will be the Lead CLRN for your study.

London (South)

For information about support and advice available through the Lead CLRN and the CLRNs for participating sites see http://www.crncc.nihr.ac.uk/about_us/processes/csp. A map showing the CLRNs is available at http://www.crncc.nihr.ac.uk/about_us/ccrn.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/10/2013
Planned end date: 22/07/2016
Total duration:
Years: 2 Months: 9 Days: 22

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

☐ NHS organisations in England	
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Social care organisations	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent hospitals	
☑ Educational establishments	1
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	1

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

King's College London Standard Indemnity

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

King's College London Standard Indemnity

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

King's College London Standard Indemnity

Please enclose a copy of relevant documents.

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

- Dementia of any severity
- As not all residents who have cognitive impairment will have a formal diagnosis of dementia, residents who have cognitive impairment will also be included. Cognitive impairment will be determined through interview and meeting the criteria of stages four to seven on the Global Deterioration Scale (Reisberg et al. 1982).

REFERENCES:

Reisberg, B., Ferris, S. H., de Leon, M. J. and Crook, T. (1982) 'The Global Deterioration Scale for assessment of primary degenerative dementia', The American journal of psychiatry, 139(9), 1136-1139.

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

This project is designed to develop a palliative care intervention for people with dementia in residential care homes. There is evidence that people with dementia can benefit from palliative care yet have poor access to it (Moriarty et al. 2012). This is part due to recognising palliative care need in a population who have difficulties communicating and due to the lack of evidence-based palliative care interventions for people with dementia (Moriarty et al. 2012, Mitchell et al. 2012).

In order to develop an intervention aimed at improving care home staff to identify palliative care problems for people with dementia, this has to be developed with people with dementia. This is in order to ensure that the specific needs of those with dementia are included and that the intervention is designed to be effective with this population group.

This study proposes developing an outcome measure as an intervention for people with dementia. It is important that outcome measures are developed and tested for the population that they are aimed for in order to ensure the validity of the instrument (Terwee et al. 2007). As such, the aims of this study could not be achieved without the participation of those with dementia.

Outcome measures are more valuable if they can work along the entire disease trajectory from the early stages until death (Evans et al. 2013). Additionally, the disease progresses it becomes more challenging to identify palliative care need as people with the illness lose the ability to communicate need (Aminoff et al. 2004). As such, an outcome measure that is validated for people with all stages of dementia including the advanced stages where people will lack capacity is required.

While there are already palliative care outcome measures validated for people with advanced dementia (Aminoff et al. 2004, Volicer et al. 2001), no outcome measure has been developed for use by care home staff as an intervention to aid identification of palliative care problems in people with dementia.

REFERENCES:

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', Archives of Gerontology and Geriatrics, 38(2), 123-30.

Evans, C. J., Benalia, H., Preston, N. J., Grande, G., Gysels, M., Short, V., Daveson, B. A., Bausewein, C., Todd, C. and Higginson, I. J. (2013) 'The selection and use of outcome measures in palliative and end-of-life care research: the MORECare international consensus workshop', Journal of Pain and Symptom Management.

Mitchell, S. L., Black, B. S., Ersek, M., Hanson, L. C., Miller, S. C., Sachs, G. A., Teno, J. M. and Morrison, R. S. (2012) 'Advanced dementia: state of the art and priorities for the next decade', Annals of Internal Medicine, 156(1 Pt 1), 45-51.

Moriarty, J., Rutter, D., Ross, P. D. S. and Holmes, P. (2012) End of life for people with dementia living in care homes, London: Social Care Institute for Excellence.

Terwee, C. B., Bot, S. D., de Boer, M. R., van der Windt, D. I. A., Knol, D. L., Dekker, J., Bouter, L. M. and de Vet, H. C.

(2007) 'Quality criteria were proposed for measurement properties of health status questionnaires', Journal of Clinical Epidemiology, 60(1), 34-42.

Volicer, L., Hurley, A. C. and Blasi, Z. V. (2001) 'Scales for evaluation of End-of-Life Care in Dementia', Alzheimer Disease and Associated Disorders, 15(4), 194-200.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

The doctoral student is an experienced clinician in mental health and particularly dementia, will assess capacity.

Other members of the research team who will assess capacity will be experienced researchers and clinicians in palliative care with experience in assessing capacity.
If required, members of the research team will receive training on assessing mental capacity before recruitment.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

◉ Yes ○ No

If Yes, please indicate the nature of this benefit. You may refer back to your answer to Question A24.

This intervention aims to improve the detection of palliative care needs, enable prompt treatment of symptoms while reducing burdensome interventions and avoidable admissions. The effectiveness, of this intervention, however, has not yet been established. Nonetheless, it is hoped that the intervention will be effective.

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

◉ Yes ○ No

If Yes, please explain how the research will achieve this:

This is an intervention aimed to improve the identification of palliative care need in people with dementia, in order to improve symptom management and quality of life for this population group.

B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

◉ Yes ○ No

If Yes, please give an assessment below. Highlight any risk, burden or discomfort specific to these participants and say what will be done to minimise it. You may refer back to your answers to Questions A22 and A23.

It is not anticipated that the intervention will put the participants at any significant risk. It is also not expected that the study will burden the participants in anyway as no active involvement is required from the participants.

Participants case notes will be accessed and measures completed by care home staff who know them well will be carried out, which could breach their privacy. All data will be pseudonymised in order to protect resident privacy.

Questions B7 and B8 apply to any participants recruited in England and Wales.

B7. What arrangements will be made to identify and consult persons able to advise on the presumed wishes and feelings of participants unable to consent for themselves and on their inclusion in the research?

The process of consent will follow the Mental Capacity Act (2005). As it is anticpated that many of the particpants may have fluctuating capacity or may lose capacity during the study, advice from consultees will be gained for all participants including those who have capacity and provide informed consent (Gysels et al. 2013). Involving consultees will include the following steps:

- Prior to approaching residents, the study will be advertised in the care home to ensure that family and friends of dementia are aware of the project and contact the researcher team to advise if they have any concerns or do not wish for their family member to particpate.

- A coffee morning will be arranged to give family or friends the opportunity to meet the research team, ask questions about the project and request that their friend or family member is not approached to particpate.

- Eligible residents, identified by the care home staff and consenting to be approached, will be approached by the research team and the study will be explained. Those residents who do not have the capacity to consent to be approached by the research team (are not communicative) or are unable to provide informed consent to the study will be deemed not to have capacity to consent.

- Care home staff will be asked to identify personal consultees for all participants who are able to and willing to provide informed consent as well as those who do not have capacity. Personal consultees will be identified based on the resident's pre-specified wishes (i.e. lasting/enduring power of attorney) or based on the knowledge of the care home staff (i.e. a family member or friend who knows the resident well and visits the care home regularly).

- Care home staff will be asked to contact personal consultees to gain permission for them to be approached by the research team. A member of the research team will contact those who agree to be contacted. Information will be provided on the role of the personal consultee. Written advice will be obtained from personal consultees.

- At least two attempts over a period of three weeks will be allowed to contact personal consultees. If there has been no response over this time, then a professional consultee will be approached to provide advice.

- Where friends or family decline to be a personal consultee but are not against the resident particpating, the opinion of a professional consultee will be sought. A professional consultee will also be used for those residents who do not have any person who is able to be a personal consultee. This includes paid professionals (e.g. solicitors) who have lasting power of attorney.

- The professional consultee will be a person who has knowledge of research but is completely independent from the project. It may be that the professional consultee will be paid for the services and time they provide to the study to recompense for time and expenses incurred. Should this be the case then a formal contract will be drawn up ensuring that there are no conflict of interests.

REFERENCES:

Gysels, M., Evans, C. J., Lewis, P., Speck, P., Benalia, H., Preston, N. J., Grande, G. E., Short, V., Owen-Jones, E. and Todd, C. J. (2013) 'MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research', Palliative Medicine.

Mental Capacity Act (2005) Chapter 9, London: HMSO.

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

B8. Is it possible that a participant requiring urgent treatment might need to be recruited into research before it is possible to identify and consult a person under B7?

○ Yes ◉ No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants and what arrangements will be made to seek consent from the participant (if capacity has been recovered) or advice from a consultee as soon as practicable thereafter.

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

It is not anticipated that it will be necessary to continue to consult personal or professional consultees. Information on how to contact the research team will be given to all personal consultees in case they wish to discuss the project or withdraw the resident from the study.

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

The research team will meet with all participants prior to the opinion of consultees being sought. This will include those residents who have not been able to consent to meet with a member of the research team. The justification for this is that it is preferable to engage with the participants as best as possible before approaching consultees.

The study will be discussed with participants using a one-sided information sheet. Where residents clearly show reluctance to participate even if they do not have capacity, their wishes will be respeced and they will not be included for participation.

If residents do not have capacity but there is no indication that they do not wish to participate, then they will be asked whether there is anyone who they would like consulted. Where possible, this wish will be respected.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

It is likely that capacity could flucutate or that residents could lose capacity over the duration of the study. As such, informed consent will be obtained from residents but advice from a consultee (either personal or professional) will also be obtained (Gysels et al. 2013).

REFERENCE:

Gysels, M., Evans, C. J., Lewis, P., Speck, P., Benalia, H., Preston, N. J., Grande, G. E., Short, V., Owen-Jones, E. and Todd, C. J. (2013) 'MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research', Palliative Medicine.

B12-1. What will be the criteria for withdrawal of participants?

Resident participants will remain in the study for the duration unless:

- they express the wish to withdraw from the study
- the personal or professional consultee wishes the resident to withdraw from the study
- the resident dies, this is a possible and likely outcome given the frailty of expected frailty of the population.

In all cases of withdrawal, the data that has already been collected will be used unless the participant or consultee requests otherwise. In some cases it may not be possible to withdraw the data and this will be explained on the patient information leaflet.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

Prior to the study commencing, the research team will hold a coffee morning in the care home to provide information to residents and unpaid carers. The research team will also meet with each participant to explain the study and provide the opportunity for the resident to decline to participate. This will be done even if the resident does not have capacity.

In order to minimise burden, once the participants have consentened (and the consultees have advised), the participants will not be approached again. If, however, the researchers become aware of participants wishing to withdraw from the study (either from care home staff, consultees, unpaid carers or directly from residents), the research team will meet with the resident. If the resident wishes, they will be withdrawn from the study.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

The overall aim of this study is to develop an intervention to improve the quality of lives and symptom management of people with dementia. It is hypothesised that by implementing an outcome measure that assesses the palliative care needs of residents, one of the process changes will be improved care planning. This includes decisions about preferred place of care and advance decisions. It is therefore hypothesised that this intervention will, if anything, improve adherence to any advance decisions.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Investigator identifier	Research site	Investigator Name
IN1 ☐	○ NHS site ◉ Non-NHS site	Forename: Clare Middle name: Family name: Ellis-Smith Email: alexandra.c.ellis-smith@kcl.ac.uk Qualification (MD...): MSc Mental Health Services Research BSc Occupational Therapy Country: UNITED KINGDOM

Institution name: King's College London
Department name: Department of Palliative Care, Policy and Rehabilatation, King's College London
Street address: Bessemer Road
Town/city: London
Post Code: SE5 9PJ
Country: UNITED KINGDOM

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS	[redacted] NHS TRUST	[redacted] E-mail: [redacted]
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS	[redacted] PCT	Individuals have not yet been identified. E-mail:
○ NHS (England) ○ NHS (outside England) ◉ Non-NHS	Three residential care homes in the London Borough of [redacted]	Individual care homes have not yet been finalised. Local authority approval will be obtained through the RGF process. Contact for this process is [redacted] E-mail [redacted]

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◯ Chief Investigator

◯ Sponsor

○ Study co-ordinator
⊗ Student
○ Other – please give details
○ None

Access to application for training purposes *(Not applicable for R&D Forms)*
Optional – please tick as appropriate:

☒ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .....

Print Name: DR. BARBARA DAVIDSON

Date: 14/08/2013 *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co–sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature: .....

Print Name: Keith Brennan

Post: Director of Administration (Health Schools)

Organisation: King's College London

Date: 13/08/2013 *(dd/mm/yyyy)*

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature: .....

Print Name: DR BARBARA DAVESON

Post: RESEARCH FELLOW

Organisation: KING'S COLLEGE LONDON

Date: 14/08/2013 *(dd/mm/yyyy)*

Academic supervisor 2

Signature: .....

Print Name: DR CATHERINE EVANS

Post: CLINICAL LECTURER

Organisation: KING'S COLLEGE LONDON

Date: *(dd/mm/yyyy)*

Academic supervisor 3

Signature: .....

Print Name: PROFESSOR IRENE HIGGINSON

Post: HEAD OF DEPARTMENT - PALLIATIVE CARE, POLICY AND REHABILITATION

Organisation: KING'S COLLEGE LONDON

Date: 14/08/2013 *(dd/mm/yyyy)*

Health Research Authority

NRES Committee London - South East
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars,
Lewins Mead,
Bristol
BS1 2NT

Telephone: (0117) 3421382

18 November 2013 – Re-issued 06.05.14

Dr Barbara Daveson
Research Fellow
King's College London, Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ

Dear Dr Daveson

Study title:	**The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes**
REC reference:	**13/LO/1339**
IRAS project ID:	**132542**

Thank you for your letter of 11 November 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Assistant Mr Wai Yeung, nrescommittee.london-southeast@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Participant Information Sheet: District nurse/GP participant information sheet for phase 3 focus group	2	01 November 2013
Participant Information Sheet: Care home staff participant information sheet for phase 2 focus groups	2	01 November 2013
Participant Information Sheet: Care home staff participant information sheet for phase 2 cognitive interviews	2	01 November 2013
Participant Information Sheet: Care home staff participant information sheet for phase 3 focus groups	2	01 November 2013
Participant Information Sheet: Care home staff participant information sheet for phase 3 participant observation	2	01 November 2013
Participant Information Sheet: District nurse/GP participant information sheet for phase 2 focus group	2	01 November 2013
Participant Information Sheet: Brief participant information sheet for residents	3	11 November 2013
Participant Information Sheet: Consultee information sheet	3	11 November 2013
Participant Information Sheet: Participant information sheet for residents who have capacity to consent	3	11 November 2013
Participant Information Sheet: participant information sheet for unpaid carers phase 2 focus groups	3	11 November 2013
Participant Information Sheet: District nurse/GP participant information sheet for phase 3 participant observation	2	01 November 2013
Participant Information Sheet: participant information sheet for unpaid carers phase 3 focus groups	3	11 November 2013
Referees or other scientific critique report: Internal peer review, Researchers meeting Cicely Saunders Institute		30 January 2013
Other: Palliative care Outcome Scale (POS)	2 (staff reported version)	
Other: Integrated Palliative care Outcome scale (IPOS)	staff reported version	
Response to Request for Further Information		
Interview Schedules/Topic Guides	Example of case vignette, Version 1	06 August 2013
Other: Letter to the General Practitioner for unpaid carers	1	06 August 2013
Other: Non NHS SSI: King's College, London	1	14 August 2013
Other: recruitment and consent flowchart	1	26 July 2013
Other: Distress protocol	1	12 August 2013
Other: Supporting letter for lay person		13 August 2013

Covering Letter		14 August 2013
REC application		13 August 2013
Protocol		12 August 2013
Investigator CV		12 August 2013
Participant Consent Form: for residents who have capacity to consent	1	13 August 2013
Participant Consent Form: for unpaid carers	1	13 August 2013
Participant Consent Form: for care home staff	1	13 August 2011
Participant Consent Form: for GPs and district nurses	1	13 August 2013
Participant Consent Form: Consultee declaration form	1	13 August 2013
GP/Consultant Information Sheets		06 August 2013
Evidence of insurance or indemnity		29 July 2013
Questionnaire: Global Deterioration Scale		
Questionnaire: Support Team Assessment Schedule		
Questionnaire: Mini Suffering State Examination		
Advertisement: Coffee Morning Poster,	1	06 August 2013
Other: Summary CV for supervisor (student)		12 August 2013
Other: Summary CV for student		12 August 2012
Other: Summary CV for supervisor - Professor Irene Higginson		12 August 2013
Other: Study timeline	1	06 August 2013
Other: Data collection points and timetable for phase	1	06 August 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

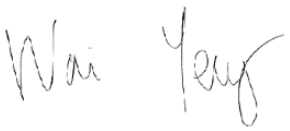
Further information is available at National Research Ethics Service website > After Review

13/LO/1339	Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely



REC Assistant

pp Professor David Caplin
Chair

Email:nrescommittee.london-southeast@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments [if final opinion was confirmed was given at a meeting]*

"After ethical review – guidance for researchers"

Copy to: *Mr Keith Brennan*
Dr Zoe Harris, King's College Hospital NHS Foundation Trust

NRES Committee London - South East

Attendance at Sub-Committee of the REC meeting

Committee Members:

Name	*Profession*	*Present*	*Notes*
Professor David Caplin	Physicist	Yes	
Mrs Vera Hughes	Training Consultant	Yes	
Mr Roy Sinclair	Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Rajat Khullar	Committee Coordinator

National Research Ethics Service

NHS Health Research Authority

NOTICE OF SUBSTANTIAL AMENDMENT (non-CTIMP)

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) available in the Integrated Research Application System (IRAS) at http://www.myresearchproject.org.uk or on the EudraCT website at https://eudract.ema.europa.eu/document.html.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.

Further guidance is available at http://www.nres.nhs.uk/applications/after-ethical-review/notification-of-amendments/.

Details of Chief Investigator:

Name:	Dr Barbara Daveson
Address:	King's College London Cicely Saunders Institute Bessemer Road Denmark Hill, London
Postcode:	SE5 9PJ
Telephone:	020 78485565
Email:	barbara.daveson@kcl.ac.uk
Fax:	020 78485517

Full title of study:	The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes
Lead sponsor:	King's College London
Name of REC:	London – South East
REC reference number:	13/LO/1339
Name of lead R&D office:	King's College Hospital

Date study commenced:	Not yet commenced
Protocol reference *(if applicable)*, current version and date:	Protocol Version 4, 12 August 2013
Amendment number and date:	2nd amendment (first substantial) – 31/03/14

Type of amendment (indicate all that apply in bold)

(a) Amendment to information previously given on the REC Application Form

Yes ~~*No*~~

If yes, please refer to relevant sections of the REC application in the "summary of changes" below.

(b) Amendment to the protocol

~~*Yes*~~ ***No***

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes ~~*No*~~

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?

~~*Yes*~~ ***No***

Summary of changes

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

1. **Changes to recruitment and gaining informed consent from unpaid carers and paid professional participants: phase two and phase three focus groups (A27-1, A29, A31):**

   Unpaid carers:
   As described in the REC application, we propose holding a coffee morning in the care homes in order to advertise the project, and provide residents and carers with the opportunity to ask questions. At the time of the phase 2 coffee morning, we will share the PISs for the phase 2 focus group for unpaid carers (amended and attached) and the first draft of POS-Dem (developed from the first phase of the study and attached). At the phase 3 coffee morning, we will share the PISs for the phase 3 focus group for unpaid carers.

   It is proposed that during the coffee mornings we will collect the names and contact details (address/email and telephone number) of those unpaid carers who are interested in participating in the focus groups (attached). We will ask their permission to contact them directly to arrange the focus groups. We will ask unpaid carers to specify preferred days of the week and times of the day (and those least convenient) so that we are able to arrange the focus group to be convenient for the majority of interested unpaid carers. We believe that by contacting the unpaid carers directly and only with their permission, we will reduce any burden on care home staff having to approach and confirm focus group details on behalf of the research team. However, if any potential participants would like to take part but are unwilling to provide their contact details, we will request that the care home staff forward letters and liaise with unpaid carers on behalf of the research team.

   Once the focus groups have been arranged, invitations (post or email) will be sent to unpaid carer participants with information about the focus groups (attached). We will then follow this up with a telephone call to confirm whether potential participants may be able to attend. This will be to plan for the focus groups and catering. Approximately one week before the focus group, a confirmation letter/email (attached) will be sent along with information for the focus group. These will include: (i) the PIS (amended), (ii) POS-Dem (draft) (attached), (iii) case vignettes (amended and attached).

   Paid professionals:
   Paid professionals will be already familiar with the project and eligible participants, are for the most part, in contact with the research team. Focus groups are being arranged in collaboration with them ensuring that the most convenient time for all participants is arranged.

   Approximately one week before the focus group, a confirmation email or letter will be sent to the participants (attached) along with information for the focus groups: (i) the

phase 2 focus groups for paid professionals, (ii) POS-Dem (draft), (iii) the case vignettes. Telephone conversations and planned face-to-face meetings will continue in order to plan the focus groups at a convenient time for all and confirm attendance.

2. Additional members of the research team (A18):

The following people may be assisting in the focus groups. This will involve gaining informed consent from paid professionals and unpaid carers, observing the focus groups and making notes during the focus group. Notes taken will be de-identified at the time of making notes (i.e. using initials instead of full names). The notes will be used to supplement the audio recordings. The additional team members may also be involved in assisting any participants who may require any individual support as required.

- Caty Pannell – name already provided in the site specific assessments
  Senior Research Nurse
  Kings' College London, Cicely Saunders Institute

  Expertise and training in obtaining consent:
  Good Clinical Practice Training
  Sage and Thyme training
  Extensive experience in recruiting and taking informed consent

- Dr Lesley Henson
  BuildCARE PhD Clinical Training Fellow
  King's College London, Cicely Saunders Institute

  Expertise and training in obtaining consent:
  Good Clinical Practice Training
  Internal training on taking consent to be provided by senior research nurse

- Melinda Smith
  Research Assistant
  King's College London, Cicely Saunders Institute

  Expertise and training in obtaining consent:
  Experience in recruiting and taking informed consent
  Good Clinical Practice Training

- Anna Bone
  Research Assistant
  King's College London, Cicely Saunders Institute

  Expertise and training in obtaining consent:
  Experience in recruiting and taking informed consent
  Good Clinical Practice Training
  Internal training received from senior research nurse

- Dr Barbara Daveson, the CI of the study may also assist in this aspect of the study but we have not provided her details again as she is already a member of the research team

Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

List of enclosed documents

Document	*Version*	*Date*
Participant information sheet for unpaid carers phase 2 focus groups	Version 4	31/03/2014
Unpaid carers contact details for focus groups	Version 1	01/04/2014
Case vignettes	Version 2	31/03/2014
POS-Dem (draft)	Version 1	03/04/2014
Unpaid carer invitation letter for phase 2 focus group	Version 1	31/03/2014
Unpaid carer confirmation letter for phase 2 focus group	Version 1	31/03/2014
Paid professionals letter of confirmation for phase 2 focus group	Version 1	01/04/2014
CV for Caty Pannell		17/01/2014
CV for Dr Lesley Henson		24/03/2014
CV for Melinda Smith		25/03/2014
CV for Anna Bone		04/12/2013

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator: .....

Print name: DR BARBARA DAVESON

Date of submission: .....

Declaration by the sponsor's representative

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules about delegated authority should be adhered to.

- I confirm the sponsor's support for this substantial amendment.

Signature of sponsor's representative: .....Keith Brennan.....

Print name: Keith Brennan

Post: Director of Research Management

Organisation: King's College London

Date: 02/04/2014

NHS
Health Research Authority

NRES Committee London - South East
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars,
Lewins Mead,
Bristol
BS1 2NT

Tel: (0117) 3421382
Fax: (0117) 3420445

17 April 2014

Dr Barbara Daveson
Research Fellow
King's College London, Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ

Dear Dr Daveson

Study title:	**The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes**
REC reference:	**13/LO/1339**
Amendment number:	**1**
Amendment date:	**02 April 2014**
IRAS project ID:	**132542**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter of invitation to participant: Unpaid carer_invitation letter to phase 2 focus group	1	31 March 2014
Anna Bone CV		
Unpaid carers contact details for focus groups_	1	01 April 2014
Caty Pannell CV		

Paid professional confirmation letter for phase 2 focus group_	1	01 April 2014
Notice of Substantial Amendment (non-CTIMPs)	1	02 April 2014
POS-Dem version	1	03 April 2014
Melinda Smith CV		
Focus group case vignettes_	2	31 March 2014
Participant Information Sheet: Unpaid carer participant information sheet_phase2 focus group	4	31 March 2014
Unpaid carer_confirmation letter for phase 2 focus group_version	1	31 March 2014
Lesley Henson_CV		

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

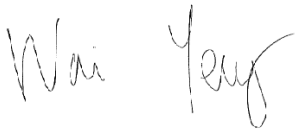
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

13/LO/1339:	**Please quote this number on all correspondence**

Yours sincerely



Mr Wai Yeung - Research Ethics Committee (REC) Assistant

pp Professor David Caplin
Chair

E-mail: nrescommittee.london-southeast@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Zoe Harris, King's College Hospital NHS Foundation Trust*
Mr Keith Brennan

A Research Ethics Committee established by the Health Research Authority

NRES Committee London - South East

Attendance at Sub-Committee of the REC meeting

Name	*Profession*	*Capacity*
Professor David Caplin	Physicist	Lay
Mr Guy Gardener	Retired Assistant Chief Constable	Lay Plus

Also in attendance:

Name	*Position (or reason for attending)*
Mr Rajat Khullar	REC Manager

National Research Ethics Service

NHS Health Research Authority

NOTICE OF SUBSTANTIAL AMENDMENT (non-CTIMP)

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) available in the Integrated Research Application System (IRAS) at http://www.myresearchproject.org.uk or on the EudraCT website at https://eudract.ema.europa.eu/document.html.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.

Further guidance is available at http://www.nres.nhs.uk/applications/after-ethical-review/notification-of-amendments/.

Details of Chief Investigator:

Name:	Dr Barbara Daveson
Address:	King's College London Cicely Saunders Institute Bessemer Road Denmark Hill, London
Postcode:	SE5 9PJ
Telephone:	020 78485565
Email:	barbara.daveson@kcl.ac.uk
Fax:	020 78485517

Full title of study:	The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes
Lead sponsor:	King's College London
Name of REC:	London – South East
REC reference number:	13/LO/1339

Name of lead R&D office:	King's College Hospital
Date study commenced:	April 2014
Protocol reference *(if applicable)*, current version and date:	Protocol Version 4,12/08/2013
Amendment number and date:	2nd substantial amendment – 21/11/2014

Type of amendment (indicate all that apply in bold)

(a) Amendment to information previously given on the REC Application Form

Yes *No*

If yes, please refer to relevant sections of the REC application in the "summary of changes" below.

(b) Amendment to the protocol

Yes *No*

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes *No*

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?

Yes ***No***

Summary of changes

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Dr Barbara Daveson, the Chief Investigator for this project is due to go on maternity leave. The expected dates that she will be on leave for are 24/11/2014 to approximately the beginning of May 2015.

Dr Daveson is delegating CI responsibility to Dr Catherine Evans, the second supervisor for this PhD project, for the duration of her maternity leave.

Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

List of enclosed documents

Document	*Version*	*Date*
CV for Dr Catherine Evans		November 2014
REC form Part D, signed by Catherine Evans		November 2014

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator: .....

Print name: DR BARBARA DAVIDSON

Date of submission: 21 November 2014.....

Declaration by the sponsor's representative

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules about delegated authority should be adhered to.

- I confirm the sponsor's support for this substantial amendment.

Signature of sponsor's representative: .....Keith Brennan.....

Print name: Mr Keith Brennan.....

Post: Director of Research Management and Innovation

Organisation: King's College London

Date: 10/12/2014.....

Health Research Authority

NRES Committee London - South East
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars,
Lewins Mead,
Bristol
BS1 2NT

Tel: (0117) 3421382

16 December 2014

Dr Barbara Daveson
Research Fellow
King's College London, Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ

Dear Dr Daveson

Study title:	**The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes**
REC reference:	**13/LO/1339**
Amendment number:	**2**
Amendment date:	**11 December 2014**
IRAS project ID:	**132542**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP) [POS-Dem_Notice of Substantial Amendment_2nd amendment_December2014]		11 December 2014
Other [REC form part D with all authorisations]		10 December 2014
Other [Catherine Evans_NMC registration]		
Summary CV for Chief Investigator (CI) [Dr Catherine		

Evans_CV_November 2014]		

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

13/LO/1339:	Please quote this number on all correspondence

Yours sincerely

Mr Wai Yeung
Research Ethics Committee (REC) Assistant

pp Professor David Caplin

E-mail: nrescommittee.london-southeast@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Zoe Harris, King's College Hospital NHS Foundation Trust*
Mr Keith Brennan

A Research Ethics Committee established by the Health Research Authority

NRES Committee London - South East

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Professor David Caplin	Physicist	Yes	
Mrs Stephanie Cooper	Solicitor	Yes	
Professor John Eastwood	Consultant Renal Physician	Yes	
Professor Robin MacKenzie	Director Medical Law & Ethics	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Wai Yeung	REC Assistant

Notice of Amendment IRAS Version 4.0.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
A palliative care intervention for people with dementia in care homes

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[✓] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

(•) Yes ( ) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

(•) Yes ( ) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
Clare Ellis-Smith will be involved in the design, recruitment and carrying out the research.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Catherine	Evans
Work Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		
	Denmark Hill, London		
PostCode	SE5 9PJ		
Email	catherine.evans@kcl.ac.uk		
Telephone	02078485579		
Fax	02078485517		

Full title of study:	The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes
Lead sponsor:	King's College London
Name of REC:	NRES Committee London - South East
REC reference number:	13/LO/1339
Name of lead R&D office:	King's College Hospital NHS Foundation Trust
Date study commenced:	April 2014
Protocol reference (if applicable), current version and date:	Version 5 24/03/2015
Amendment number and date:	3rd substantial amendment

Type of amendment

(a) Amendment to information previously given in IRAS

◉ Yes ○ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Please see revised protocol with highlighted changes. The protocol has been revised based on the changes detailed below.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

(●) Yes ( ) No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Information sheets have been changed to reflect the changes detailed below.
Additional supporting documents are provided.

Is this a modified version of an amendment previously notified and not approved?

( ) Yes (●) No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

We are requesting a review of a substantial amendment to the study design. The study is a student project for a PhD. The amendments requested incorporate recommendations made by senior external and internal examiners for the PhD upgrade process from MPhil to PhD – successfully completed. The recommendations made by the examiners intended to improve the study feasibility and strengthen the focus of the study.

The amendments requested pertain to the final phase of the study (phase 3). Phase 3 is a mixed-methods study where the tool under development (POS-DemA) is used in the field to test its utility in detecting and managing symptoms and problems in people with dementia. We have strengthened the focus of the study to the development and feasibility evaluation of POS-DemA as an assessment tool to improve detection of symptoms and problems, and communication between health and social care. We have reduced the focus on developing POS-DemA as an outcome measure in this study.

All amendments are highlighted in the attached protocol and corresponding study documents. The amendments requested include:

A11. Secondary research questions
The overall aim and secondary research questions are unchanged, but we have reduced the number of measurement properties tested. In particular, construct validity and internal consistency are no longer examined. Acceptability, feasibility and mechanisms of action will be explored in greater depth.

The name of POS-Dem is changed to POS-Dem- Assessment (POS-DemA). This change reflects the increase in focus on developing POS-DemA as an assessment tool, not an outcome measure at this stage. The title of the project is therefore changed to:

'The Palliative care Outcome Scale for Dementia – Assessment (POS-DemA): an intervention for people with dementia living in residential care homes'. All Participant Information Sheets and consent forms are amended to reflect this change.

A13. Design and methodology
There are some changes to methodology to reflect the change of focus:
- Each resident now receives POS-DemA for a period of 12 weeks rather than four months. This time period is a sufficient length to obtain data required for the study and improves the study feasibility of delivery within available resources. This information is detailed in all participant information sheets (PIS).

- For clarity the protocol objective describing 'interpretability' is now incorporated under 'mechanisms of action' and is no longer a separate objective

-To explore the feasibility and processes of using POS-DemA in care homes we are incorporating serial interviews with each care home manager or senior staff member. The interviews will be conducted approximately every four weeks (up to five times) for the duration of phase 3. The interviews will explore the feasibility and acceptability of using POS-DemA in routine care and the mechanisms of action. Each manager/ senior care home staff will be

recruited once for all the serial interviews that they participate in. The PIS and consent form for serial interviews are provided in the supporting documents.

- Care home staff completing POS-DemA for a resident are asked to complete a utility questionnaire to further explore the acceptability, feasibility and mechanisms of action. The utility questionnaire is included at the end of the POS-DemA tool. The utility questionnaire is completed anonymously (to the research team) by care home staff each time they complete POS-DemA for a resident as part of the POS-DemA data collection. Written information about the purpose of the utility questionnaire and how it is used is provided to care home staff before they complete it.

The current version of POS-DemA (version 2) with the attached utility questionnaire is provided in supporting documents. Please note that this version of POS-DemA is subject to change prior to its use with resident participants. These changes are based on the results of the cognitive interviews currently being conducted. Any changes made are to improve comprehension and clarity of POS-DemA to care home staff. Therefore, unless the committee would specifically like to review the finalised version of POS-DemA (POS-DemA version 3), we do not anticipate submitting this for approval prior to its use with resident participants.

- As reported in the initial application, focus groups are conducted with unpaid carers, and paid professionals towards end of phase 3 (following the majority of resident participants having received POS-DemA for 12 weeks). To enable carers and professionals participation, we would offer individual semi-structured interviews for those unable to attend the focus groups.

-Participant observation of GPs and district nurse consultations with care home staff regarding participating residents are to increase to up to eight observations at each care home for the duration of phase 3. Where possible, half of these will occur in the first three months and half will occur in the second three months of phase 3. While one participant (GP, district nurse or care home staff member) may be observed in up to eight meetings, it is more likely that the observations will be divided between different participants

- Case note review and data extraction of residents care home records. The data extraction is informed by the previous phases of the study. Data for extraction comprises: POS-DemA assessments, care plans, professional reviews, and referrals to services. Case note reviews occur at baseline and at 12-week endpoint for each resident. Case note review may also occur up to every four weeks for the 12 week duration for each participating resident. A data extraction form is used and detailed in the supporting documentation. Copies of POS-DemA with the accompanying utility questionnaire are made in the care home and securely transferred to the lead site for data entry and analysis. Care homes are reimbursed for the copy expenses. All POS-DemA assessments are anonymised before analysis using a unique identifier.

- Demographic data is collected for residents including age, diagnosis of dementia (yes/no), type of dementia, severity of dementia (Functional Assessment Staging (FAST) (Reisberg 1988), gender, ethnicity, religion, medical diagnoses, and medications. This information is collected at initial case note review and in collaboration with staff.

- Demographic data is collected for paid professionals: professional qualification(s) and year(s) obtained, job title/role, years of experience, ethnicity and first language. This is collected from participants at time of taking consent using demographic data collection forms.

- Demographic data is collected for unpaid carers: age, relationship to resident, ethnicity and gender. This is collected from participants at time of taking consent using demographic data collection forms.

A13: Design and methodology, A57/A58 primary and secondary outcome measures
- As reported in the initial application, two outcome measures are used at baseline and at the final time point (week 12) of receiving POS-DemA for each resident. These measures are selected to describe the participant population and examine the effect of using POS-DemA on resident outcomes. The selected measures are a functional measure, Barthel Index (Mahoney 1965) and an agitation measure, Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield et al 1989). MSSE and STAS are no longer administered. Copies of Barthel Index and CMAI are provided in supporting documentation.

A17.2 Exclusion criteria
- Residents receiving specialist palliative care are no longer excluded. There is no ethical reason to exclude them as this in an observational study. Moreover, residents receiving specialist palliative care are likely to benefit most from the use of an assessment tool. This group often have the most complex care needs and complex symptom presentation. Data on receipt of specialist palliative care is extracted in the case notes review.

B7: recruitment and consent of residents
- The processes of recruitment and consenting of older adults with cognitive impairment in a care home is anticipated as resource intense (Goodman et al. 2011). To facilitate timely recruitment the research team (PhD student and a

research nurse) will be supported by a research practitioner from the Clinical Research Network South London (CRN SL) Division 5 (primary care). The research practitioner is experienced in recruitment. Their activities will include working with care home staff to screen for eligibility, taking informed consent for residents with capacity to consent, working with care home staff to approach personal consultees for advice on resident participation, and taking advice from professional or nominated consultees.

- It is anticipated that some eligible participants who lack capacity will not have a personal consultee e.g. no next of kin. In these instances the CRN SL Division 4 (DeNDRoN) will provide a research practitioner to be a nominated consultee. Research practitioners employed by the CRN SL are independent from the research study. The research practitioners have expertise on the design and conduct of research and the implications of resident participation. Their research knowledge means they are well-placed and well-informed to act as a nominated consultee. To facilitate their role as a nominated consultee regarding whether a resident would have wished to participate in the study and indications of contraindication, the research practitioner (who may not be a clinician) will meet residents were appropriate and review care home case notes in discussion with care home staff. The research practitioners will not be directly reimbursed for residents recruited to this study and there is therefore no incentive for them to advise that residents should participate.

- To reduce care home burden, the research team have written two letters of approach to personal consultees. They will be sent by care home staff to potential personal consultees as described in the original REC application. These letters are provided in the supporting documentation.

References:
Cohen-Mansfield, J., Marx, M. S. and Rosenthal, A. S. (1989) 'A description of agitation in a nursing home', Journal of Gerontology, 44(3), M77-M84.

Goodman, C., Baron, N. L., Machen, I., Stevenson, E., Evans, C., Davies, S. L. and Iliffe, S. (2011) 'Culture, consent, costs and care homes: enabling older people with dementia to participate in research', Aging & Mental Health, 15(4), 475-481.

Mahoney, R. I. and Barthel, D. W. (1965) 'Functional Evaluation: the Barthel Index (BI)', Maryland State Medical Journal, (14), 56-61.

Reisberg, B. (1988) 'Functional assessment staging (FAST)', Psychopharmacology Bulletin, 24(4), 653.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Proposal	5	24/03/2015
Brief participant information sheet for residents	4	15/03/2015
Participant information sheet for residents who have capacity to consent	4	15/03/2015
Resident participant consent form for residents who have capacity to consent	2	15/03/2015
Consultee information sheet	4	15/03/2015
Consultee declaration form	2	15/03/2015
Personal consultee letter of approach	1	24/03/2015
Personal consultee second letter of approach	1	24/03/2015
Participant information sheet for unpaid carers phase 3 focus groups	4	15/03/2015
Participant consent form for unpaid carers	2	15/03/2015

Care home manager/ Senior staff participant information sheet for phase 3 serial interviews	1	15/03/2015
Care home staff participant information sheet for phase 3 participant observation	3	15/03/2015
Care home staff participant information sheet phase 3 focus groups	3	15/03/2015
Consent form for care home manager/ senior staff phase 3 serial interviews	1	15/03/2015
Participant consent form for care home staff	2	15/03/2015
District nurse/ GP participant information sheet phase 3 focus group	3	15/03/2015
District nurse/ GP participant information sheet phase 3 participant observation	3	15/03/2015
Participant consent form for GPs and district nurses	2	15/03/2015
Participant consent form for participant observation	1	15/03/2015
POS-DemA manual and assessment with utility questionnaire	2	15/03/2015
POS-DemA assessment with utility questionnaire	2	15/03/2015
Barthel Index		
Cohen-Mansfield Agitation Inventory		
Letter to General Practitioner	2	15/03/2015
Letter to Genereal Practitioner for unpaid carers	2	15/03/2015
Case note review data extraction form	1	24/03/2015
Data collection form paid professionals	1	24/03/2015
Data collection form unpaid carers	1	24/03/2015

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Dr Catherine Evans on 08/04/2015 08:31.

Job Title/Post:	Clinical lecturer
Organisation:	KCL
Email:	catherine.evans@kcl.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mr Keith Brennan on 08/04/2015 10:31.

Job Title/Post:	Director of Research Management & Innovation

Organisation:	King's College London
Email:	keith.brennan@kcl.ac.uk

Health Research Authority
National Research Ethics Service

NRES Committee London - South East
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

22 April 2015
Modified April 2015

Dr Barbara Daveson
Research Fellow
King's College London
King's College London, Cicely Saunders Institute
Bessemer Road
Denmark Hill, London
SE5 9PJ

Dear Dr Daveson

Study title:	**The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes**
REC reference:	**13/LO/1339**
Amendment number:	
Amendment date:	**08 April 2015**
IRAS project ID:	**132542**

The Substantial Amendment proposed amendment to study design.

The above amendment was reviewed on 21 April 2015 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
GP/consultant information sheets or letters [Letter to the General Practitioner for unpaid carers_Version 2_15032015]		15 March 2015
GP/consultant information sheets or letters [Letter to the General Practitioner_Version 2_15032015]		15 March 2015
Notice of Substantial Amendment (non-CTIMP) [POS-Dem_3rd substantial AmendmentForm_ReadyForSubmission]		08 April 2015
Other [Case Note Review Data Extraction Form_Version		

1_24032015]		
Other [Consultee declaration form_Version 2_15032015]		
Other [Data Collection Form - Paid professionals_Version 1_24032015]		
Other [Data Collection Form - Unpaid Carers_Version 1_24032015]		
Other [Personal consultee_letter of approach_version1_24032015]		
Other [Personal consultee_second letter of approach_version1_24032015]		
Other [POS-DemA assessment version 2 with utility questionnaire_15032015]		
Other [POS-DemA Manual and assessment version 2 with utility questionnaire_15032015]		
Other [Barthel Index]		
Other [CohenMansfield Agitation Inventory]		
Participant consent form [Consent form for care home manager senior staff phase 3 serial interviews_Version 1_15032015]		
Participant consent form [Participant consent form for care home staff_Version 2_15032015]		
Participant consent form [Participant consent form for GPs and district nurses_Version 2_15032015]		
Participant consent form [Participant consent form for participant observation_Version 1_15032015]		
Participant consent form [Resident participant consent form for residents who have capacity to consent_Version 2_15032015]		
Participant consent form [Participant consent form for unpaid carers_Version 2_15032015]		
Participant information sheet (PIS) [Participant information sheet for unpaid carers_phase3 focus group_Version 4_15032015]		
Participant information sheet (PIS) [Brief participant information sheet for residents_Version 4_15032015]		
Participant information sheet (PIS) [Care home manager senior staff participant information sheet for phase 3 serial interviews_Version 1_15032015]		
Participant information sheet (PIS) [Care home staff participant information sheet_phase 3 focus groups_Version 3_15032015]		
Participant information sheet (PIS) [Care home staff participant information sheet_phase 3 participant observation_Version 3_15032015]		
Participant information sheet (PIS) [Consultee information sheet_Version 4_15032015]		
Participant information sheet (PIS) [District nurse and GP participant information sheet_phase 3 participant observation Version 3]		15 March 2015
Participant information sheet (PIS) [District nurse and GP participant information sheet_phase 3 focus group Version 3]		15 March 2015
Participant information sheet (PIS) [Participant information sheet for residents who have capacity to consent Version 4]		15 March 2015
Research protocol or project proposal	5	24 March 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

13/LO/1339:	**Please quote this number on all correspondence**

Yours sincerely

PP K. Southwood

On behalf of Professor David Caplin
Chair

E-mail: nrescommittee.london-southeast@nhs.net

Copy to: *Dr Zoe Harris, King's College Hospital NHS Foundation Trust*
Mr Keith Brennan

NRES Committee London - South East

Attendance at Sub-Committee of the REC meeting on 21 April 2015

Committee Members:

Name	*Profession*	*Present*	
Dr Ashok Bhiman	Consultant Psychiatrist	Yes	
Professor David Caplin	Physicist	Yes	
Ms Stephanie Cooper	Retired Solicitor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*	
Mr Wai Yeung	REC Assistant	

Appendix F. Local authority research governance

London RGF Alliance Common Proposal Form

Title of Research Study(this must be the title you use when making contact with service users/participants):
The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes

As this project may be published in a number of separate articles, it will not be possible to use this title for publications. Where possible, we will make reference to this title in all publications.

Background: What are the aims and objectives of the research (this should include what the main question to be answered is?, what other projects/studies have been carried out in this area, (if any) and how will your research add to any previous work undertaken)?

Background:
Palliative care for people with dementia:
There is growing recognition that a palliative care approach with its aim of improving quality of life and symptom management can benefit people with dementia (Moriarty et al. 2012). Despite this, people with dementia have poor access to palliative care (Moriarty et al. 2012). As a result people with dementia may have poor symptom management and may also be subjected to burdensome interventions to prolong life that may not be beneficial or in keeping with the goals of comfort (Morrison and Siu 2000).

One barrier to accessing palliative care is the difficulties in identifying symptoms and problems in people with dementia, many of whom have significant communication problems (Aminoff et al. 2004). There is also little high-quality research into palliative care interventions for people with dementia, particularly in the UK (Goodman et al. 2010). There is a need to develop interventions that enable prompt treatment of distressing symptoms and access to specialist care (Goodman et al. 2010, Moriarty et al. 2012, Mitchell et al 2012).

Residential care home research:
Dementia and cognitive impairment is one of the primary disorders associated with admission to care homes (Bebbington et al. 2001). In the UK, residential care homes are not required to have on-site nursing and these care homes therefore rely on primary and community healthcare services. Residential care home staff who may have had no clinical training are therefore required to identify palliative care need in the people they care for despite the complexities and challenges this poses. Additionally, care home staff need to be able to communicate these problems to healthcare professionals in order to access healthcare for the residents they care for.

There is, however, evidence that there are challenges to integrated working between social and health care (Davies et al. 2011, Gage et al. 2012). Facilitators of integrated working include shared assessment and care frameworks and shared documentation.

An intervention that can aid residential care home staff identify palliative care problems is required. Additionally, this intervention should aid integrated working between care home staff and community healthcare staff in order for it to have an effect on patient care.

Outcome measures as an intervention:
Outcome measures can be used in practice to aid identification of problems, facilitate communication, screen for problems, aid shared decision making and monitor response to treatment (Higginson and Carr 2001). This study proposes that implementing an outcome measure to be completed by care home staff, and providing clear guidance and signs for completion, can aid care home staff identify and screen for problems, and communicate problems to healthcare professionals. It is proposed that it may also facilitate shared decision-making between care home staff and healthcare staff.

Aim
To develop and establish the clinical utility of an intervention, POS-Dem, to aid residential care home staff screen, identify and monitor palliative care problems; and communicate these to primary healthcare staff in order to improve symptom management and quality of life in residents with dementia.

Objectives
1. To adapt the Palliative care Outcome Scale (POS) (Hearn and Higginson 1999) for use by care home staff with people with dementia (POS-Dem).
2. To establish the face/content validity of POS-Dem.
3. To test construct validity of POS-Dem
4. To determine the test-retest reliability of POS-Dem
5. To test the internal consistency of POS-Dem
6. To establish the acceptability of POS-Dem to care home staff and primary care staff (GPs and community nurses).
7. To establish the feasibility of using POS-Dem in practice
8. To determine the interpretability of POS-Dem
9. To gain an understanding of the underlying mechanisms of the intervention and test these through examination of the process and outcome measures.

References

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', *Archives of Gerontology and Geriatrics*, 38(2), 123-30.

Bebbington, A., Darton, R. and Netten, A. (2001) *Care Homes for Older people: Volume 2 admissions, needs and outcomes. The 1995/96 National Longitudinal Survey of Publicly-Funded Admissions*, Personal Social Services Research Unit, University of Kent.

Davies, S., Goodman, C., Bunn, F., Victor, C., Dickinson, A., Iliffe, S., Gage, H., Martin, W. and Froggatt, K. (2011) 'A systematic review of integrated working between care homes and health care services', *BMC Health Services Research*, 11(1), 320.

Gage, H., Dickinson, A., Victor, C., Williams, P., Cheynel, J., Davies, S. L., Iliffe, S., Froggatt, K., Martin, W. and Goodman, C. (2012) 'Integrated working between residential care homes and primary care: a survey of care homes in England', *BMC Geriatrics*, 12(1), 71.

Goodman, C., Evans, C., Wilcock, J., Froggatt, K., Drennan, V., Sampson, E., Blanchard, M., Bissett, M. and Iliffe, S. (2010) 'End of life care for community dwelling older people with dementia: an integrated review', *International Journal of Geriatric Psychiatry*, 25(4), 329-37.

Hearn, J. and Higginson, I. (1999) 'Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group', *Quality in Health Care*, 8(4), 219-227.

Higginson, I. J. and Carr, A. J. (2001) 'Using quality of life measures in the clinical setting', *BMJ*, 322(7297), 1297-1300.

Mitchell, S. L., Black, B. S., Ersek, M., Hanson, L. C., Miller, S. C., Sachs, G. A., Teno, J. M. and

Morrison, R. S. (2012) 'Advanced dementia: state of the art and priorities for the next decade', *Annals of Internal Medicine*, 156(1 Pt 1), 45-51.

Moriarty, J., Rutter, D., Ross, P. D. S. and Holmes, P. (2012) *End of life for people with dementia living in care homes*, London: Social Care Institute for Excellence.

Morrison, R. S. and Siu, A. L. (2000) 'Survival in end-stage dementia following acute illness', *JAMA*, 284(1), 47-52.

Proposed Start Date: 01/10/2013	
Estimated Completion Date: 22/07/2015	

Lead Researcher/ Project Leader	
Name: Dr Barbara Daveson (Chief Investigator)	Tel: 02078485565
Organisation: King's College London	Fax:02078485517
Job Title: Research Fellow	Email: barbara.daveson@kcl.ac.uk
Address: King's College London, Cicely Saunders Institute, Bessemer Road, Denmark Hill, London, SE5 9PJ	
Please give indication of lead researcher's experience and/or relevant qualifications: BMus (MUSTHY) PhD	
Names(s) and address(es) of other Researcher(s) who will be involved: Clare Ellis-Smith – doctoral student who will be carrying out the majority of the data collection and analysis BuildCARE PhD Training Fellow King's College London, Cicely Saunders Institute Bessemer Road Denmark Hill London, SE59PJ Academic supervisors: Dr Barbara Daveson – Research Fellow Dr Catherine Evans – Clinical Lecturer Professor Irene Higginson – Head of Department – Palliative Care, Policy and Rehabilitation All based on King's College London, Cicely Saunders Institute	

Research Sponsor/Partner (External)	
Name: Mr Keith Brennan	Tel:02078486960
Organisation: King's College London	Fax: 02078486394
Job Title: Director of Research Management and Director of Administration (Health Schools)	Email: keith.brennan@kcl.ac.uk
Address: Room 1.8 Hodgkin Building, Guy's Campus, London, SE1 4UL	
Internal Research Sponsor (e.g. this will usually be a Service Manager/Line manager/Supervisor who has agreed to the research project)	
Name: These details have not yet been finalised	Tel:
Organisation:	Fax:
Job Title:	Email:
Address:	
Research Commissioner/Funder (Organisation funding or responsible for commissioning this research)	
Contact Person: Cicely Saunders International	**Tel**: 020 78485580
Organisation: Cicely Saunders International	**Fax**:
Job Title:	**Email:**
Address: Cicely Saunders Institute Bessemer Road London, SE5 9PJ	
Resources/Budgets:	
Financial cost of the whole research project: This PhD research project is part of a wider project, BuildCARE, funded by Cicely Saunders International and The Atlantic Philanthropies. All research costs will be funded by this project.	
If cost is in staff days, then number of full-time days: n/a	
Social Services staff time required (please record separately from researcher time): It is proposed that staff at three residential care homes will participate in the study. In order to gain input from a wide a range of staff as possible all grades of care home staff will be invited to participate.	

Care home staff as participants in the study:

- Gaining consent to participate in each phase of the study: This will be up to but not exceeding five occasions for each care home staff participant for the duration of the study lasting 10-15 minutes per session
- Focus groups and/or interviews: This will be up to but not exceeding three occasions for each care home staff participant lasting 60-120 minutes
- On two occasions in each care home, care home staff may be observed meeting with GPs or district nurses. This will be part of routine work and no additional work will be required.
- Outcome measurement completion: Two measures completed prior to intervention being introduced and at the end of the intervention for each resident participant. Approximately 20-40 minutes at each time point per resident.
- Use of POS-Dem: Care home staff using the intervention for a period of four months. This will involve completing POS-Dem for each participating resident for this period of time. It is anticipated that this will be completed on a monthly basis but will be determined at the time of the focus groups. Care home staff may then use the completed measure to work with primary healthcare professionals.

Care home staff as collaborators in the research project:

- It is likely that the project will be presented to the care home staff and that some collaboration work will be carried out. This will allow care home staff to ask questions and contribute to the implementation of the project. Particularly in the early stages but throughout the project, meetings are likely to be carried out with the managers of the care homes and staff regarding planning and implementation.
- Hosting a coffee morning for residents and family/friends (120-180 minutes). This will be organised and facilitated by the research staff in collaboration with care home staff. It is likely that two coffee mornings through the duration of the project will be carried out.
- Care home staff – aiding recruitment of resident and unpaid carer participants: One care home staff to go through the list of care home residents, identify eligible participants and introduce to research team. Also to identify potential unpaid carers and gain permission for them to be contacted by research team. Finally, to identify consultees to provide advice as to whether residents with dementia should participate as stipulated by the Mental Capacity Act (2005).

Reference

Mental Capacity Act (2005) Chapter 9, London: HMSO.

Methodology and Techniques

Please describe the recruitment process (how participants are going to be selected and approached):

Care home staff, GP and district nurse participants:

- Prior to the study commencing, the research team will meet with care home staff, district nurses and GPs to discuss the study and potential collaboration and participation.
- Once care homes, GPs and district nursing teams have been identified, recruitment of participants will be carried out. Care home staff, GPs and district nurses will be provided with participant information sheets prior to participating. They will be asked to sign a written informed consent form.

Residents with dementia or cognitive impairment – see flowchart

- A coffee morning or equivalent will be held in each participating care home in order to provide information about the study and allow residents and unpaid carers (family and friends) to ask questions about the study. Written information about the study will also be made available at this time. This will also give residents and unpaid carers the opportunity to request that the resident is not approached.
- A member of the research team will meet with a senior member of staff to go through the resident list. The senior member of the care home staff will be asked to identify potentially eligible resident participants and introduce a member of the research team to them.
- If the resident is in agreement, the project will be discussed with resident participants using a single page information sheet. This will be left with the resident along with a more detailed participant information sheet for family or friends.
- If the resident has capacity, a member of the research team will return to gain consent.
- Those residents who do not have the capacity to consent to meeting with a member of the research team, or those that are unable to provide informed consent (based on a capacity assessment) will be deemed not to have capacity.
- Those residents who appear reluctant to participate even if they do not have capacity will not be included.
- For those residents who have consented to participate and have capacity as well as those that do not have capacity, a personal consultee will be approached to provide advice on whether to the resident should participate.
- Care home staff will be asked to identify personal consultees for all participants who are able to and willing to provide informed consent as well as those who do not have capacity. Personal consultees will be identified based on the residents' pre-specified wishes (i.e. lasting/enduring power of attorney) or based on the knowledge of the care home staff (i.e. a family member or friend who knows the resident well and visits the care home regularly).
- Care home staff will be asked to contact personal consultees to gain permission for them to be approached by a member of the research team. Information will be provided on the role of the personal consultee. Written advice will be obtained from the personal consultees
- At least two attempts over a period of three weeks will be allowed to contact personal consultees. If there has been no response over this time, then a professional consultee will be approached
- Where friends and family decline to be a personal consultee but are not against the resident participating, the opinion of a professional consultee will be sought. A professional consultee will also be used for those residents who do not have any person who is able to be a personal consultee
- The professional consultee will be a person who has knowledge of research but independent from the project.

Unpaid carers:

- The project will be advertised in the care home and through a coffee morning
- Care home staff will be asked to identify potentially eligible unpaid carers and request their permission to be approached by a member of the research team.
- Written information will be provided and written informed consent gained.

What research methods will you use in collecting your data? E.g. telephone survey, interview, questionnaire, case file audit, focus group, internet survey, video/audio interviews etc

There will be three phases to this study – see study timeline

Phase one:
Phase one will be a narrative synthesis of the literature to adapt the Palliative care Outcome Scale (POS) (Hearn and Higginson 1999) for people with dementia (POS-Dem) and develop guidance on completing POS-Dem.

Phase two:
In this phase focus groups will be carried out with unpaid carers in order to ascertain what components of palliative care needs are important to be included in POS-Dem. Unpaid carers will be consulted on their capacity as proxies for people with dementia or cognitive impairment as well as their capacity as carers. A PowerPoint presentation may be used to facilitate this focus group.

Focus groups will also be carried out with care home staff (all grades), GPs and district nurses. It is proposed that these focus groups will be inter-disciplinary. The focus groups will be carried out in order to determine what components of POS-Dem professionals consider important. Additionally, vignettes will be presented to this focus group in order to understand how POS-Dem may be used to aid practice.

Once these focus groups have been transcribed and analysed, POS-Dem will be adapted based on the analysis of the data.

Cognitive interviews will then be carried out with a sample of care home staff participants. The grade of these staff will be determined at the time of the focus group but care home staff for the cognitive interviews will be purposively sampled to represent years of experience, first language, and amount of training. Cognitive interviews will employ the techniques of 'think aloud' and 'probing' in order to gain an understanding of how care home staff understand and interpret the questions and guidance.

The final version of POS-Dem will be developed based on the analysis of cognitive interviews.

Phase three – see phase 3 data collection time points:

This will be a pilot study where POS-Dem will be implemented for a period of four months with participating residents. It is anticipated that POS-Dem will be used on a monthly basis with participating residents but this will be determined in the previous focus groups.

Prior to POS-Dem being implemented and at the end of implementation, two outcome measures will be used. These will be determined in the first phase of the study but may be:

- Support Team Assessment Schedule (STAS) (Higginson and McCarthy 1993) or equivalent

- Mini Suffering State Examination (MSSE) (Aminoff et al. 2004) or equivalent

At the first time point, POS-Dem will be repeated within five days on a group of stable residents.

Case notes for participating residents will be reviewed for the month prior to the intervention being implemented and the last month of it being implemented.

On two occasions at each care home, a consultation between a GP or district nurse and the care home staff will be observed.

Focus groups will be carried out at the end of the intervention period with unpaid carers and with paid professionals in order to understand how acceptable the intervention is for these groups, how feasible it is to be used in routine practice, and in order to understand how it may work to improve resident outcomes.

References

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', *Archives of Gerontology and Geriatrics*, 38(2), 123-30.

Hearn, J. and Higginson, I. (1999) 'Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group', *Quality in Health Care*, 8(4), 219-227.

Higginson, I. J. and McCarthy, M. (1993) 'Validity of the support team assessment schedule: do staffs' ratings reflect those made by patients or their families?', *Palliative Medicine*, 7(3), 219-228.

Exactly what participant/user information is required?

Demographic information on all participants will be required.

Initial focus groups and interviews will be carried out so that unpaid carers and paid professionals can inform the development of POS-Dem, based on their expertise. This is to ensure that POS-Dem is developed to detect problems that are considered important by all these groups. These focus groups and interviews will also be conducted to ensure so that POS-Dem is developed to support care, with an understanding of how it may work in practice and the context that it is to be used.

The focus groups/ interviews following the pilot will be to gain an understanding of how acceptable the intervention was for unpaid carers and paid professionals. These focus groups will also be carried out to understand how feasible POS-Dem is to be used in routine work and how it might work to improve resident outcomes.

Participant observation will be carried out in order to understand how POS-Dem may be used to facilitate communication.

Use of the outcome measures prior to and post the pilot study will be carried out to understand whether the introduction of POS-Dem improves patient outcomes. As this is a pilot study, however, it will not be powered to detect significant improvement. These outcome measures will also be used to test some of the measurement properties of POS-Dem.

The review of case notes prior to the intervention and in the last month of intervention will be used to gain an understanding of how the intervention may change practice to improve resident outcomes (process measures). Data obtained from the focus group will be used to inform which process measures are taken from the case notes but process measures are likely to include: Gold Standard Registration, integrated care plans, documented decisions regarding place of care, medication reviews, and referrals to specialist services.

Repeat POS-Dem scores over the period of the intervention will also be used to establish the measurement properties of POS-Dem as well as understand whether resident outcomes are improved for the duration of the intervention. At two time points, the time taken to complete POS-Dem will be recorded. This will be to further inform the feasibility of routinely using POS-Dem as part of care.

Are the participants known to the researcher? Yes ☐ No ☑

If Yes, in what capacity?

While the participants are not currently known to the researcher, the researcher has been establishing contact with residential care homes and some care homes have agreed to participation. Similarly, contact is currently being made with district nurses and GP surgeries.

How will you select your sample and what is your proposed sample size?

Sample selection:

Care home staff will be selected from participating residential care homes
GPs and district nurses will be selected from those who provide healthcare to participating care homes.
Unpaid carers will be recruited on whether they consider themselves to be a relative or good friend of a resident who has dementia or cognitive impairment living in a participating care home.
Residents of dementia will be recruited based on the following inclusion criteria:

- Diagnosis of dementia – any severity
- Cognitive impairment initially based on care home staff's decision that they may be eligible and then on interview with one of the members of the research team. Cognitive impairment will be determined through interview on the Global Deterioration Scale stages four to seven (Reisberg et al.1982)

Sample size:
All focus groups will be approximately 8-15 members in size. Three focus groups with paid professionals and three focus groups with unpaid carers will be carried out in both phase two and phase three. It is anticipated that theoretical saturation will be reached with this number of focus groups. If, however, theoretical saturation is not reached, focus groups will continue until theoretical saturation is reached or all resources have been exhausted.

This will result in a sample size of up to 45 unpaid carers (15 in each care home) for each phase (phases two and three). Approximately 45 care home staff (15 in each care home) for focus groups and interviews (depending on the size of care home, numbers of staff attending, and theoretical saturation).

Up to 10 primary healthcare professionals (approximately 3-4 per care home) for each phase (phases two and three).

65 Residents will be recruited. The number recommended as a minimum for reliability studies is 50 (de Vet et al. 2011, Terwee et al. 2007). An additional 30% (15) is included in the sample size to account for attrition.

References

de Vet, H. C., Terwee, C. B., Mokkink, L. B. and Knol, D. L. (2011) *Measurement in medicine,* Cambridge: Cambridge University Press.

Reisberg, B., Ferris, S. H., de Leon, M. J. and Crook, T. (1982) 'The Global Deterioration Scale for assessment of primary degenerative dementia', *The American journal of psychiatry,* 139(9), 1136-1139.

Terwee, C. B., Bot, S. D., de Boer, M. R., van der Windt, D. I. A., Knol, D. L., Dekker, J., Bouter, L. M. and de Vet, H. C. (2007) 'Quality criteria were proposed for measurement properties of health status questionnaires', *Journal of Clinical Epidemiology,* 60(1), 34-42.

Willis, G. B. (2005) *Cognitive interviewing: A tool for improving questionnaire design,* SAGE Publications, Incorporated.

Will participants receive payment for participating? Yes ☐ No ☑

If yes, please provide details:

No participants will receive payment however out-of-pocket expenses such as travel costs will be reimbursed. Additionally, refreshments will be provided at coffee mornings and focus groups.

Certificates of participation will be provided to care homes and also offered to individual paid professionals for their CVs to acknowledge the contribution they have made.

Where will the research be conducted?

Data collection will predominantly be carried out in the three participating care homes. Some interviews may be carried out at other sites such as GP surgeries.

All analysis will be carried out at King's College London.

Will participants be clearly and fully informed of the purpose of the research?
Yes ☑ No ☐

How are you planning to analyse/interrogate research data?

All focus groups and interviews will be transcribed verbatim. Deductive content analysis will be used to analyse focus groups, interviews and participant observations.

Quantitative data analysis will include the following:

Demographic data:
These will be presented as summary statistics to describe the sample

POS-Dem scores and outcome measures (construct validity):

POS-Dem scores and both other outcome measure scores will be analysed at T0 for all participants in order to establish construct validity. As there is no gold standard, POS-Dem will be divided into two constructs based on the hypotheses that it is testing:

a) Physical and emotional symptoms
b) Care and support needs

These constructs will be compared using measures with established validity and reliability determined from reviews of measures (Parker and Hodgkinson 2011, van Soest-Poortvliet et al. 2012b, van Soest-Poortvliet et al. 2012a, van Soest-Poortvliet et al. 2011) and previous palliative care outcome measure validation studies e.g. Hearn and Higginson (1999). Validity for each construct will be measured through Spearman's rho correlation coefficients. It is likely that these may include:

- Mini-suffering state examination (MSSE) (Aminoff et al. 2004) or equivalent
- Support Team Assessment Schedule (STAS) (Higginson and McCarthy 1993) or equivalent

Outcome measures (underlying mechanisms of action and effectiveness of POS-Dem):
Mean/median scores with standard deviations/interquartile ranges for overall scores and each item will be calculated for the two validated outcome measures before and after the intervention. Mean change between before and after time points will be calculated to determine the effect of the intervention on patient symptoms and palliative care problems.

POS-Dem scores (internal consistency):
Cohen's kappa will be used to establish the internal consistency of POS-Dem.

Repeat POS-Dem scores (test-retest reliability):
Cohen's kappa will be used to calculate test-retest reliability as this measure adjusts for chance agreements (de Vet et al. 2011). In order to establish test-retest reliability, scores of those residents who have been stable between T0 and T0+i will be recorded. Stability will be established by ensuring that there have not been any periods of illness requiring consultations with any health practitioners or medication changes, and those residents that have not been stable will be excluded. There is no guidance on how much time should have elapsed between measurements for test-retest reliability and de Vet et al. (2011) and recommend a period of approximately two weeks but suggest that time elapsed should be based on an estimate of how stable the population is expected to be balanced with avoiding recall of the participants completing the measures (Terwee et al. 2007). As this population is a frail one, only a short time period of three to seven days will be used.

Repeat POS-Dem scores (underlying mechanisms of action and effectiveness of POS-Dem):
Mean/median scores with standard deviations/interquartile ranges for overall scores and each item on POS-Dem will be calculated for each of the six time points. Mean change between time points will be calculated in order to determine the effect on resident palliative care problems of implementing POS-Dem.

POS-Dem scores (feasibility):
Feasibility will be examined through the number of times that POS-Dem was completed when it should have been and the number of times that this was missed. At T0 and T4, for each resident participant, the length of time that it takes a staff member to complete POS-Dem will be recorded. No guidance could be found for what is an acceptable length of time for a measure to take but Hearn and Higginson (1999) in the development of POS found that it never took longer

than 10 minutes for either patient or staff to complete POS with a mean time of 5.7 minutes for staff at first assessment. It is proposed that in phase II of the study, care home staff will be asked what an acceptable time taken to complete would be and the actual time taken to complete will be compared to this. Additionally, qualitative data will also be collected through focus groups.

Process measures:
Process measures taken from the previous month before intervention and the final month of the intervention will be compared. These data will be summed for the entire resident participant population and care home subgroups to determine any process changes from the implementation of the intervention.

References

Aminoff, B. Z., Purits, E., Noy, S. and Adunsky, A. (2004) 'Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination', *Archives of Gerontology and Geriatrics*, 38(2), 123-30.

de Vet, H. C., Terwee, C. B., Mokkink, L. B. and Knol, D. L. (2011) *Measurement in medicine*, Cambridge: Cambridge University Press.

Hearn, J. and Higginson, I. (1999) 'Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group', *Quality in Health Care*, 8(4), 219-227.

Higginson, I. J. and McCarthy, M. (1993) 'Validity of the support team assessment schedule: do staffs' ratings reflect those made by patients or their families?', *Palliative Medicine*, 7(3), 219-228.

Parker, D. and Hodgkinson, B. (2011) 'A comparison of palliative care outcome measures used to assess the quality of palliative care provided in long-term care facilities: a systematic review', *Palliative Medicine*, 25(1), 5-20.

Terwee, C. B., Bot, S. D., de Boer, M. R., van der Windt, D. I. A., Knol, D. L., Dekker, J., Bouter, L. M. and de Vet, H. C. (2007) 'Quality criteria were proposed for measurement properties of health status questionnaires', *Journal of Clinical Epidemiology*, 60(1), 34-42.

van Soest-Poortvliet, M. C., van der Steen, J. T., Zimmerman, S., Cohen, L. W., Klapwijk, M. S., Bezemer, M., Achterberg, W. P., Knol, D. L., Ribbe, M. W. and de Vet, H. C. (2012a) 'Psychometric properties of instruments to measure the quality of end-of-life care and dying for long-term care residents with dementia', *Quality of Life Research*, 21(4), 671-84.

van Soest-Poortvliet, M. C., van der Steen, J. T., Zimmerman, S., Cohen, L. W., Munn, J., Achterberg, W. P., Ribbe, M. W. and de Vet, H. C. (2011) 'Measuring the quality of dying and quality of care when dying in long-term care settings: a qualitative content analysis of available instruments', *Journal of Pain and Symptom Management*, 42(6), 852-63.

van Soest-Poortvliet, M. C., van der Steen, J. T., Zimmerman, S., Cohen, L. W., Reed, D., Achterberg, W. P., Ribbe, M. W. and de Vet, H. C. (2012b) 'Selecting the Best Instruments to Measure Quality of End-of-Life Care and Quality of Dying in Long Term Care', *Journal of the American Medical Directors Association*.

Who will be Involved

Please provide details of the participants who will be involved (e.g. children in need, Adults with Disabilities, older people, Voluntary sector organisations):

- People with dementia or cognitive impairment living in dementia-registered residential care homes
- Family members or friends (unpaid carers) who consider themselves to be carers of people with dementia or cognitive impairment living in the participating residential care homes
- Care home staff of all levels of seniority including support staff
- GPs who provide healthcare to the participating residential care homes
- District nurses who provide input to participating residential care homes

Will stakeholders be involved in all stages of the study? (i.e. research that is carried out with or by people who use services, rather than research that simply gathers information from participants) Please give details

This project has been presented to an older adult mental health service user and carer group who has provided feedback and advice on the study and the intervention. Additionally, a lay person who has been a carer for a relative with advanced dementia living in a care homes has been involved in the study. She has provided suggestions and feedback on the overall study. She has also read and provided feedback and comments the participant, consultee and unpaid carer participant information sheets.

This study will also use a collaborative approach drawing on the principles of the participatory approach. As such, in coffee mornings and presentations to all participants, all participants will be asked to give their input into the study. Care home staff will be consulted with regards to their knowledge about this sector and how to conduct and facilitate this research in care homes.

All participants will be recruited in order to inform the development of the intervention and to ensure that the intervention is designed to work in the care home context and work for the participants who may be using it in the future.

What geographical areas will be covered as part of your research?(e.g. name of area, wards, borough wide, super output areas, LAP areas):

London Borough of [redacted]

Ethics

How will you obtain explicit informed consent from your target group?(e.g. signed consent form)

- Written informed consent will be gained from all participants (see attached for consent forms)
- Where a resident has capacity and consents and where a resident does not have capacity, consultees will be approached for advice regarding participation (see attached for consultee information sheet and consent form)
- Written informed consent will be obtained for all paid professionals

Is there any potential risk of harm to participants or yourself? Yes ☑ No ☐

If so (a) what are the risks
(b) What do you intend to do to reduce them?

Resident participants

- We have sought a design that is minimally intrusive for people with dementia who may be frail with comorbidities. As we do not yet know how accurate POS-Dem will be, there is a small risk that the intervention may correctly or incorrectly detect problems resulting in increased treatments for residents. POS-Dem is not designed however to replace clinical judgement but rather alert clinicians to possible problems and/or symptoms.
- Taking part in the study will involve reading and recording resident records including personal and medical information. In order to protect confidentiality, this information will be anonymised and will only be identifiable by a identify code stored separately from the data.
- When conducting research with vulnerable adults, there is always a risk of safeguarding concerns being raised. Should this be the case then [redacted] local policies for reporting safeguarding vulnerable adults will be followed. All participants will be informed that while confidentiality will be respected, should it be revealed that a vulnerable adult is at risk, then this information will need to be reported.

Unpaid carers

- Participating in focus groups regarding the care of family and friends may explore sensitive topics and be distressing. Participants need not answer questions and may withdraw at any time. Where necessary a distress protocol will be followed (see attached).
- Participating in focus groups is time consuming. Times and venues will be arranged according to the preferences of the majority of participants. Light meals or refreshments will be provided to fit into time schedules.
- All focus groups will be recorded. In addition, participants will be asked whether their names can be used on the recording in order to aid analysis. Once the focus groups have been transcribed, pseudonymised codes will be used which will be stored separately from the transcripts.
- While the research team will adhere to data protection in order to ensure confidentiality, this cannot be guaranteed as other research participants may share what has been said in the focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality.

Paid professionals

- Focus groups and interviews with paid professionals will be recorded and, in the case of focus groups, participants will be asked whether their names can be used on recordings. Once the focus groups have been transcribed , pseudonymised codes will be used which will be stored separately
- While the research team will adhere to data protection in order to ensure confidentiality, confidentiality cannot be guaranteed as other research participants may share what has been said in the focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality.
- Paid professionals are busy and participating in this study will add to this burden. Times and venues will be arranged around the preferences of the majority of participants. Where participants are not able to attend focus groups, semi-structured interviews will be offered at a time and location convenient to the participants. In order to fit into busy time schedules refreshments or light meals will be provided.

Researchers:

Exploring sensitive emotional areas or dealing with distressed participants can lead to distress within the research team. The research will be conducted within the Department of Palliative Care, Policy and Rehabilitation which is a team with extensive experience in conducting

research in palliative and end-of-life care. There is informal support within the department and all the researchers will receive supervision.

We will offer participants the option of completing focus groups or interviews in a place and time that is most convenient for them. This will require researchers visiting participants in the community (most likely care homes). The department lone working policy will be followed. As such, all those working off-site in this way are required to complete a log showing where they are going to conduct an interview. All researchers will be paired with a partner to ensure that a named individual knows their whereabouts at all times.

Where appropriate, will information be made available to participants in alternative formats? (Braille, audio tape, video tape, other languages)

Resident participants:
Due to limited resources it will not be possible to use interpreters and translators and those residents who are unable to communicate in English will therefore have to be excluded. Large print leaflets will be provided for people with visual impairment and the use of visual aids will be used with those who have hearing difficulties.

All other participants:
As all participants will be asked to participate in focus groups and interviews, people who do not speak English will be excluded from the study. Such people will not be able to participate in focus groups, where we hope that the discussion will spark a better flow of ideas

Will participants be informed of your complaints procedures? Yes ☑ No ☐

A contact number for complaints is provided on participant information leaflets.

If No please explain why

Where applicable, have all research staff been CRB (Criminal Records Bureau) checked? If yes, please attach evidence

All research staff who will be collecting data will be CRB checked – please see attached.

How will the study comply with equal opportunities regulation/policy (Race, Gender, Disability, Age, Faith, Sexual orientation)?

King's College London is committed to equal opportunity and non-discriminatory practice, and this study will comply with this policy.

Where budget allows, all participants will be provided with an equal opportunity to participate in the project, and no group will be discriminated against. Unfortunately, due to budget restraints, people who do not speak English will not be able to be included in this study due to the cost of interpreters and translators.

Does the project involve four or more local authorities? Yes ☐ No ☑

If so, has the study received ADSS approval (Association of Directors of Social Services)?
Yes ☐ No ☐ (provide details if Yes)

Has the research received approval from other bodies e.g. DoH, DfES, University, College etc?
Yes ☐ No ☑

If yes, please attach the evidence :

As this project involves people who lack capacity, this study is requires NHS REC approval with a committee flagged for adults lacking capacity. This will be obtained prior to the study commencing.

R+D approval will be obtained for both participating NHS organisations ([redacted] Trust and [redacted] CCG)

Has the research been subjected to any peer review/approval?
Yes ☑ No ☐

If yes, please give details below:
This project has been reviewed by supervisors and senior research staff within Cicely Saunders Institute, King's College London.

The PhD fellowship is part of a peer reviewed external grant award, Project BuildCARE, which requires a PhD on this topic.

In the event of a compensation claim resulting from the research, are you insured?(give details below):

Yes, insurance certificate attached

Storage/Confidentiality

Will information gathered be made anonymous or pseudonymous? Yes ☑ No ☐
How will the information be stored (locked cabinets, password protected files, encrypted recordings)?

Any paper copies of study data will be stored in a locked cabinet at the Cicely Saunders Institute on the site of King's College Hospital. Any electronic data will be stored on encrypted data sticks or encrypted external hard drives within Cicely Saunders Institute, King's College London.

What are the arrangements for protecting the confidentiality of information about the participants (Encrypted files, password protected computers, anonymised, shredding)?

All data will be collected and anonymised according to the guidelines of the Department of Palliative Care, Policy and Rehabilitation, King's College London (updated April 2010). Participants will be assigned a unique identifier code (code number) at the time of data collection. These codes will be linked to person identifiable information in a research 'code book'' which will be kept in a separate locked cabinet from any copies of the data itself.

Have they researcher(s) signed a confidentiality agreement? (please attach a copy)

King's College London Confidentiality Code – see attached

Please describe how and where information will be held by the Researchers:

All data analysis will take place within the campuses of King's College London. All analyses will be undertaken by the doctoral student or members of the research team working on the project within the Department of Palliative Care, Policy and Rehabilitation, King's College London.

Will the data be used for any purposes other than the study?

Anonymised data files may be kept, as these may be used in subsequent secondary data analysis or pooled with other studies.

Once the project is completed, when and how will the original service user information, and any derived information not necessary for publication be destroyed

All pseudonymised data will be kept for seven years after the study has ended in accordance with the guidelines of the Department of Palliative Care, Policy and Rehabilitation, King' s College London. This will allow for validation of the results following publication.

Original recordings and measures will be stored for a period of seven years in a locked archived room in the Cicely Saunders Institute, King's College London. Only members of the department have access to this room. The Cicely Saunders Institute is staffed by King's College London security during the day and locked with security at night.

After seven years, original recordings and transcripts will be destroyed confidentially. Note that transcripts will not have participants' names on them.

How would you ensure compliance with the data protection legislation (See guidance)?

King's College London is required to comply with the Data Protection Act. The King's College London Data Protection Policy has been developed to comply with the Data Protection Act.

Who will own the data and reports?

King's College London

Dissemination and Feedback

In what form will your findings be presented (i.e. reports, audio tape, video tape, journal article, book)?

Thesis
Peer reviewed scientific journals
Conference presentations
Internal reports
Publication on website

Will you feedback findings to participants and stakeholders in appropriate formats(give details e.g. Braille, audio tape, video tape, other languages)

All paid professionals will be informed of the study results through a summary of the study results and details of publications.

We will not routinely inform resident participants of the findings of the study as many of the resident participants may die or have significant cognitive impairment by the end of the study. At the time of consent we will offer residents the option of receiving the findings. If a resident participant expresses a wish to be informed of the study findings we will allow for this. However, we will first ascertain the clinical status of the participants before disseminating the results.

As unpaid carers will be the carers of residents who both have participated and my not have participated in the study, it will not be possible to ascertain the medical status of all the residents who unpaid carers look after without breaching confidentiality. As such, it will not be possible to determine whether they have passed away and it would therefore not be an appropriate time to contact unpaid carers. A more passive approach of dissemination will therefore be provided, where informal carers will be advised that they can obtain the results from the care home. Copies of the summary of the results or details of how to obtain a copy will be left with the care home for this purpose.

Are you intending to publish your findings? (Reports intended for publication must be approved by the panel prior to publication)
Yes ☑ No ☐

Where will the research be published and what information will the published research include?

Peer reviewed scientific journals. These articles will detail methods that were used to collect and analyse the data, as well as the findings. Demographic data about the area, care home and individual participants will be included but no identifiable information will be used in publication.

Overall, how will the data be used to inform and improve services?

This is a project to develop a novel intervention for people with dementia in residential care homes. As this intervention is in the development stages, it is not yet known whether it will be effective and therefore be of benefit to the participants.

This is an opportunity, however, for care home staff, GPs and district nurses to inform the development of a novel intervention so as to ensure that is it acceptable and feasible for use in practice.

Supporting Documents

Please provide copies of the following documents (where appropriate) and any other accompanying information for panel approval.

Consent Form	☑	Approvals from other approving bodies	☐
Questionnaires/Surveys	☑	ADSS Approval / Application	☐
Interview Questions	☐	Researcher's confidentiality agreement	☑
Topic list	☑	Previous research	☐
Participant Information sheet	☑	Research Timetable	☑
CRB Checks	☑	Profile of lead researcher	☑

Please provide any other relevant information and documents (specify below):

The following documents are attached:
Consent form:

- Resident
- Consultee
- Unpaid carer
- Care home staff
- District nurse/GP

Questionnaire/measurements:

- Global Deterioration Scale
- Mini Suffering State Examination
- Support Team Assessment Schedule

Topic guide:

- Example of case vignette to be used in focus groups with paid professionals

Participant information sheet

- Participation sheet for residents who have capacity to consent
- Brief participant information sheet for residents
- Participant information sheet for unpaid carers phase 2 focus groups
- Participant information sheet for unpaid carers phase 3 focus groups
- Care home staff participant information sheet for phase 2 focus groups
- Care home staff participant information sheet for phase 2 cognitive interviews
- Care home staff participant information sheet for phase 3 focus groups
- Care home staff participant information sheet for phase 3 participant observation
- District nurse/ GP participant information sheet for phase 2 focus groups/interviews
- District nurse/GP participant information sheet for phase 3 focus groups/interviews
- District nurse/GP participant information sheet for phase 3 participant observation
- Consultee information sheet

All other

- CRB check for Clare Ellis-Smith
- Research protocol
- Distress protocol
- Insurance indemnity certificate
- Resident recruitment flowchart
- Study timeline
- Data collection points and timetable for phase 3
- CV for Clare Ellis-Smith
- Researcher's confidentiality agreement
- Coffee morning poster
- Letter to GP
- Letter to GP for unpaid carers

For Panel Use Only

Comments/requirements for further information

Guidance & examples

Further information about some of the headings used in the London RGF Common Proposal Form and some examples are presented below. The information provided is intended to be indicative and not exhaustive.

Title of Research Study: this must be the title you use when making contact with service users/participants as well as when publishing the research results.

Background: What are the aims and objectives of the research as well as a brief description of the rationale for the study with regard to the policy context, statutory requirements etc.This should include what the main question to be answered is, what other projects/studies have been carried out in this area, (if any) and how your research will add to any previous work undertaken.

Lead Researcher/ Project Leader: this is usually the head of the Research Team or the main researcher who is responsible for the project

Internal Research Sponsor: this will usually be a Service Manager/Line manager/Supervisor who has agreed to the research project. This person has the internal responsibility for ensuring that the research is progressing as planned and service users are safeguarded.

Research Commissioner/Funder: this refers to the organisation funding or responsible for commissioning the research.

Who will be Involved: You are required to provide details of the participants who will be involved in the research study such as service users, children in need, adults with disabilities, older people, residents, voluntary sector organisations.

Sampling and sample size: The sample is the target population of the research. It reflects the characteristics of the population from which it is drawn.

The Data Protection Act: the act gives individuals the right to know what information is held about them. It works in two ways; firstly, it states that anyone who processes personal information must comply with eight principles, that personal information is:

- Fairly and lawfully processed
- Processed for limited purposes
- Adequate, relevant and not excessive
- Accurate and up to date
- Not kept for longer than is necessary
- Processed in line with your rights
- Secure
- Not transferred to other countries without adequate protection

The second area covered by the Act provides individuals with a wide range of important rights, including the right to know what is held and of access to their personal information held on computer and most paper records as well as compensation and the prevention of processing.

Appendix G. Care home ethics application

[redacted]

Application Form for Ethical Approval

Submitted to: _____ Date submitted: _____

Chair, Research Ethics Review completed: _____

Researcher(s) notified: _____

Submit **three** copies of this form and attach the following to each form:
- your research proposal
- the participant information sheet
- the participant consent form
- any questionnaires, scales, measures, letters and phone/verbal scripts to be used
- debriefing materials

Name of investigator: Dr Barbara Daveson_____ Email: Barbara.daveson@kcl.ac.uk

Status: [redacted] Department……n/a…… Job title …n/a……

Researcher: Name …… Institution ……

Student: Name …Clare Ellis-Smith…. Institution …King's College London…

Project title: _The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes _____

Indicate here if the proposal is a procedural modification of a previously reviewed project: ~~Yes~~/No

If yes, the title of previously reviewed project:

___n/a_____

Name of student/supervisor in previous project:

_____

List changes in current project:

Source of participants:
Residents with dementia or cognitive impairment – [redacted]
Care home staff working at [redacted] – all grades and roles
[District nurse(s) and GP(s) working with residents at [redacted]]

It is proposed that [redacted] will be one of three residential care homes in [redacted] participating in this study.

Describe the project in no more than one page (summarise the background and hypotheses and detail the procedure to include the conditions experienced by the participants, stimulus, materials and response measures):

- 0 -

Background: Palliative care is considered beneficial for people with dementia as dementia is a progressive and terminal condition [1]. There is evidence to suggest that this population group experience burdensome interventions at the end of life, have poor management of symptoms of distress, and have limited access to specialist palliative care [1-3]. This is in part due to the complexities of recognising when people with dementia may benefit from a palliative care approach. It is also due to the lack of evidence-based palliative care interventions for people with dementia [4,5]. Dementia is a primary reason for admission into residential care homes accounting for 37-40% of all admissions [6]. As a consequence residential care home staff provide 24-hour care for people with dementia with support from primary and community health professionals [7]. Care home staff are therefore responsible for identifying palliative care problems and communicating these to primary health professionals, but cultural differences and lack of shared documentation act as barriers to integrated working between social care settings and health [8,9]. This study proposes adapting the validated and well-established measurement tool, the Palliative care Outcome Scale (POS) [10] or the Integrated Palliative care Outcome Scale (IPOS), for use as an intervention for people with dementia living in residential care homes.

Aim: To develop and establish the clinical utility of an intervention, POS-Dem, to aid residential care home staff screen, identify and monitor palliative care problems; and communicate these to primary healthcare staff in order to improve symptom management and quality of life in residents with dementia.

Methods: This study will draw on the principles of the participatory approach and will therefore include participatory engagement and collaborative working [11]. This approach should therefore take into account the care home culture and context with a greater understanding of how the intervention will translate into routine care. The study will be in three phases:

Phase 1: This will include a narrative synthesis of the literature in order to adapt POS/IPOS for people with dementia and develop training and guidance to accompany it. IPOS integrates two validated versions of POS (POS and POS-symptoms) into one measure and is currently being validated.

Phase 2: This will involve focus groups with unpaid carers (family and friends of residents) and focus groups with paid professionals including care home staff, GPs and district nurses. The focus groups will be used to inform the development of POS-Dem in order to understand important items for inclusion and how it might work in practice. Topic guides will be used and developed based on the narrative synthesis in phase one. Additionally, case vignettes will be used to gain an understanding of how POS-Dem may work in practice (see example). Following the analysis of focus groups, cognitive interviews will be carried out with care home staff who will be using POS-Dem. The purpose of the cognitive interviews is to establish how care home staff interpret the meaning of POS-Dem. Based on theses analyses, the final version of POS-Dem will be developed.

Phase 3: This will involve a four month pilot of POS-Dem where it will be used as part of routine care (possibly monthly but to be established in phase two). It is proposed that POS-Dem will also be used when communicating with GPs and district nurses about the healthcare needs of the residents. Prior to POS-Dem being implemented, residents' care home notes will be reviewed for the previous month. In addition, POS-Dem will be completed with all the participating residents along with two additional measures (Support Team Assessment Schedule [12] or equivalent and the Mini-Suffering State Examination (MSSE) [13] or equivalent). A repeat POS-Dem will be carried out 3-5 days later. At two time points during the intervention, a GP or district nurse consultation regarding some or all of the participant residents will be observed. Finally, at the end of the implementation phase, case notes will be reviewed for the final month and the two additional measures will be repeated. The time taken to complete POS-Dem at the first point and the last point will be recorded. On completion of the pilot phase, focus groups will be carried out with unpaid carers and paid professionals. The data obtained from all the phases of the study will be synthesised in order to achieve the following objectives:

- Face/content validity – phase 2 focus groups and cognitive interviews
- Construct validity – through comparing POS-Dem with two existing validated measures
- Test-retest reliability – through measuring the agreement between POS-Dem measures three to five days apart in a group of stable resident participants
- Internal consistency – through measurements of POS-Dem
- Acceptability of POS-Dem – through focus groups at the end of the intervention period
- Feasibility of using POS-Dem in routine care – through focus groups with paid professionals, recording the number of actual completed POS-Dem measures compared with expected numbers, recording time taken to complete
- Interpretability of POS-Dem – through focus groups and observation of consultations
- Processes and outcomes – through focus groups, case note reviews and before and after measures using existing validated measurement tools

Consent (Please see Consent Checklist)

Is prior informed consent to be obtained? Yes/~~No~~

From participants? Yes/~~No~~

Written informed consent will be obtained from care home staff participating in each element of the study i.e. phase 2 focus group, focus 2 cognitive interview, phase 3 focus group

Written informed consent will be obtained for all resident participants who have capacity to consent prior to being recruited to the pilot study. For those who do not have capacity, advice will be obtained from a personal or professional consultee adhering to the Mental Capacity Act [14]. As some of the residents who have capacity to consent, may have fluctuating capacity or lose capacity over the duration of the study, advice from a consultee (either personal or professional) will also be obtained for all residents who consent prior to them being recruited to the study [15].

Written consent will also be obtained for the district nurses and GPs participating in this study.

Describe the means of obtaining prior consent:

Care home staff, GP and district nurse participants:

- Prior to the study commencing, the research team will meet with care home staff, district nurses and GPs to discuss the study and potential collaboration and participation.
- Once care homes, GPs and district nursing teams have been identified, recruitment of individual participants will be carried out at each data collection point (e.g. phase two focus group etc.) Care home staff, GPs and district nurses will be provided with participant information sheets prior to participating. They will be asked to sign a written informed consent form for each point that they participate in the study.

Residents with dementia or cognitive impairment – see resident recruitment flowchart adapted from Scott et al [16]:

- A coffee morning or equivalent will be held in each participating care home in order to provide information about the study and allow residents and unpaid carers (family and friends) to ask questions about the study. Written information about the study will also be made available at this time. This will also give residents and unpaid carers the opportunity to request that the resident is not approached. A poster will be displayed giving details of the coffee morning
- A member of the research team will meet with a senior member of staff to go through the resident list. The senior member of the care home staff will be asked to identify potentially eligible resident participants and introduce a member of the research team to them.
- If the resident is in agreement, the project will be discussed with resident participants using a single page information sheet. This will be left with the resident along with a more detailed participant information sheet for family or friends.
- If the resident has capacity, a member of the research team will return to gain consent.
- Those residents who do not have the capacity to consent to meeting with a member of the research team, or those that are unable to provide informed consent (based on a capacity assessment) will be deemed not to have capacity.
- Those residents who appear reluctant to participate even if they do not have capacity will not be included.
- For those residents who have consented to participate and have capacity as well as those that do not have capacity, a personal consultee will be approached to provide advice on whether the resident should participate.
- Care home staff will be asked to identify personal consultees for all participants who are able to and willing to provide informed consent as well as those who do not have capacity. Personal consultees will be identified based on the residents' pre-specified wishes (i.e. lasting/enduring power of attorney)

or based on the knowledge of the care home staff (i.e. a family member or friend who knows the resident well and visits the care home regularly).

- Care home staff will be asked to contact personal consultees to gain permission for them to be approached by a member of the research team. Information will be provided on the role of the personal consultee. Written advice will be obtained from the personal consultees
- At least two attempts over a period of three weeks will be allowed to contact personal consultees. If there has been no response over this time, then a professional consultee will be approached
- Where friends and family decline to be a personal consultee but are not against the resident participating, the opinion of a professional consultee will be sought. A professional consultee will also be used for those residents who do not have any person who is able to be a personal consultee
- The professional consultee will be a person who has knowledge of research but independent from the project.

Unpaid carers:

- The project will be advertised in the care home and through a coffee morning
- Care home staff will be asked to identify potentially eligible unpaid carers and request their permission to be approached by a member of the research team.
- Written information will be provided and written informed consent gained.

If prior informed consent is not to be obtained, give reasons:

Prior informed consent will not be gained from people who lack capacity however written advice from a consultee will be obtained prior to participation.

Will participants be explicitly informed of what the researcher's role/status is? Yes/~~No~~

Prior to the study commencing, it is proposed that the doctoral student will present the study to the care home staff. This will give them the opportunity to share ideas on the research project and ask any questions.

At the start of the study, a poster will be displayed advertising a coffee morning. The photograph and contact details of the researcher, doctoral student, will be on the poster. It is proposed that the coffee morning be carried out in collaboration with the care home staff and residents and unpaid carers will be invited. This will provide unpaid carers and residents the opportunity to ask questions about the project, meet the research team and decline for themselves or relative/friend to be approached if they wish.

Will participants be told of the use to which data will be put (eg, research publication, teaching purposes, media publicity)? Yes/~~No~~

The purpose of the research and why their participation is required is explained in the patient information sheets. The plans for dissemination and publication are also provided in the participant information sheet. The consent form also advises that anonymised data may be used for teaching, educational or future research purposes.

In order to protect participants' confidentiality and anonymity, details of the study sites will not be publicised, and only broad demographic details and geographical areas will be described.

Deception
Is there any deception involved? ~~Yes~~/No

If yes, describe the deception and the reasons for its use:

Debriefing

How will participants be debriefed? Written/Oral

If they will not be debriefed, give reasons:

Formal debriefing will not take place. At the end of all focus groups and interviews, however, time will be allocated to ensure that all participants are comfortable with the process of the focus group or interview. Participants will be offered individual time immediately after the focus group in order to discuss any concern that they may have.

Participating in focus groups regarding the care of family or friends may explore sensitive topics and be distressing for unpaid carers. Where required, a distress protocol will be followed, see supporting documents for detailed distress protocol.

No interviews or focus groups will be carried out with resident participants.

Withdrawal from the investigation

Will participants be told explicitly that they are free to leave the study at any time without jeopardy? Yes/~~No~~

When and how will this be done?

All resident and unpaid carers will be informed in the participant information sheets that they do not have to participate in the study and that this will not affect the care that either they or their family or friend receive.

The participant information sheet for all participants state that participants can withdraw from the study at any time without giving reason. It is further explained that should participants withdraw from the study it may not be possible to withdraw the data that have already been provided. This is because once it has been combined it may be very difficult to withdraw individual contribution.

Confidentiality

Under the Data Protection Act information about a participant is confidential unless otherwise agreed in advance. Will confidentiality be guaranteed? ~~Yes~~/No

If yes, what steps will be taken to ensure this?

All participants who choose to participate in this study will be assured that steps will be taken to anonymise their identity. All personal data will be stored by the research team (including audio recordings) in secure locked cabinets at the Department of Palliative Care, Policy and Rehabilitation, King's College London in accordance with the Data Protection Act and the Department Data Management Guidelines. Access will be restricted and controlled.

Researchers will anonymise and code data as early as possible and to the full extent possible within the needs of the study, only essential personal information will be held. These codes will be stored in a research "code book" and stored elsewhere should it be required for research analysis or presentation of findings at a later date.

To secure access to personal information, the "code book" containing identifiable information and a unique identifier (code) assigned to individual data subjects will be maintained. This means, for example, that codes will be assigned to participants before qualitative focus groups or interviews are transcribed and quantitative data inputted.

If no, what procedures will be taken in advance of obtaining consent (how will participants be warned)?

While the research team will adhere to data protection in order to ensure confidentiality, this cannot be guaranteed as other participants may share what has been said in focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality. All participant information sheets for focus groups will advise participants that researchers will not be able to guarantee that confidentiality will be maintained.

When working with vulnerable adults, there is a potential of uncovering safeguarding vulnerable adult concerns. In this event, local policies and procedures will be followed for reporting these. In this case, [redacted] Council has a safeguarding vulnerable adult contact number for both office and out-of-office hours for urgent cases. All participants, whether professional, residents or unpaid carers, will be advised in the study information leaflet that confidentiality will be maintained at all times. It will also be explained that in the unlikely event that a vulnerable person may be at risk of harm, then confidentiality may need to be broken and local policies for reporting will need to be followed.

Protection of participants

Are the participants at risk of physical or psychological harm greater than encountered in ordinary life? Yes/~~No~~

If yes, describe the nature of the risk and steps taken to minimise it:

Residents:
As POS-Dem has not yet been validated there is a small risk that problems may be correctly or incorrectly identified. This may lead to an increase in investigations. POS-Dem, however, will not be designed to and will not replace clinical judgement. All investigations will therefore be a result of clinicians' judgement. POS-Dem may, however, help alert clinicians to possible problems.

Unpaid carers:
Participating in focus groups regarding the care of family or a friend may explore sensitive topics and be distressing. Participants need not answer any questions and may withdraw from the study at any time. Where necessary a distress protocol will be followed. See supporting documents for distress protocol.

Participating in focus groups is time consuming. Times and venues will be arranged according to the preferences of the majority of participants. Light meals or refreshments will be provided to fit into time schedules.

Paid professionals:
Paid professionals are busy and participating in this study will add to the burden. Times and venues will be arranged around the preferences of the majority of participants. Where participants are not able to attend focus groups, semi-structured interviews will be offered at a time and location convenient to the participants. In order to fit into busy time schedules refreshments or light meals will be provided.

Is the information gathered from the participants of a sensitive or personal nature? Yes/~~No~~

If yes, describe the procedures to be used for

assuring confidentiality:

Residents:
Residents' participation will mean that their care home records will be read and recorded. This includes personal and medical information. In order to protect confidentiality, this information will be anonymised and will only be identifiable by an identity code stored separately from the data.

Unpaid carers:
All focus groups will be recorded. In addition, participants will be asked whether their names can be used on the recording in order to aid analysis. Once the focus groups have been transcribed, pseudonymised codes will be used which will be stored separately from the transcripts according to data protection as already described.

While the research team will adhere to data protection in order to ensure confidentiality, this cannot be guaranteed as other research participants may share what has been said in the focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality.

Paid professionals:
Focus groups and interviews with paid professionals will be recorded and, in the case of focus groups, participants will be asked whether their names can be used on the recordings. Once the focus groups have been transcribed, pseudonymised codes will be used which will be stored separately from the transcripts.

While the research team will adhere to data protection in order to ensure confidentiality, this cannot be guaranteed as the research participants may share what has been said in the focus groups. All participants will be encouraged at the start of the focus groups to maintain confidentiality.

protecting participants from stress:

Residents:
We have sought a design that is as minimally intrusive as possible for people with dementia who may be frail with comorbidities. As such, it is not anticipated that this study will cause distress or burden to resident participants. All resident participants can withdraw from the study at any time and their consultees can withdraw residents from the study without providing explanation. This is made explicit in the participant information leaflets.

Unpaid carers:
Participating in focus groups regarding the care of family or a friend may explore sensitive topics and be distressing. Participants need not answer any questions and may withdraw from the study at any time. Where necessary a distress protocol will be followed.

At the end of all focus groups, time will be allocated to ensure that all participants are comfortable with the process of the focus group or interview. Participants will be offered individual time immediately after the focus group in order to discuss any concern that they may have.

Paid professionals:
It is not anticipated that paid professionals will be subjected to significant distress as they will be asked to share information about routine work. However, at the end of all focus groups and interviews, time will be allocated to ensure that all participants are comfortable with the process of the focus group or interview. Participants will be offered individual time immediately after the focus group in order to discuss any concerns that they may have.

Observational research

If observational research is to be conducted without prior consent, please describe the situation in which observations will take place and say how local cultural values and privacy of individuals will be taken into account:

N/A

List of supporting documents:

Research proposal
Validated questionnaires:

- Global Deterioration Scale
- Support Team Assessment Schedule
- Mini-Suffering State Examination
- Palliative care Outcome Scale
- Integrated Palliative care Outcome Scale

Coffee morning poster Version 1
Resident participant information sheets:

- Brief participant information sheet Version 2
- Participant information sheet for residents who have capacity to consent Version 2

Unpaid carer participant information sheets:

- Participant information sheet for unpaid carers phase 2 focus groups Version 2
- Participant information sheet for unpaid carers phase 3 focus groups Version 2

Care home staff participant information sheets:

- Care home staff participant information sheet for phase 2 focus groups Version 1
- Care home staff participant information sheet for phase 2 cognitive interviews Version 1
- Care home staff participant information sheet for phase 3 participant observation Version 1
- Care home staff participant information sheet for phase 3 focus groups Version 1

District nurse/GP participant information sheets:

- District nurse/GP participant information sheet for phase 2 focus groups/interviews Version 1
- District nurse/GP participant information sheet for phase 3 participant observation Version 1
- District nurse/GP participant information sheet for phase 3 focus groups/interviews Version 1

Consultee information sheet Version 2

Consent forms:

- Participant consent form for residents who have capacity to consent Version 1
- Participant consent form for unpaid carers Version 1
- Participant consent form for care home staff Version 1
- Participant consent form for GPs and district nurses Version 1
- Consultee declaration form Version 1

Letters to GPs:

- Letter to General Practitioner Version 1
- Letter to General Practitioner for unpaid carers Version 1

Study timeline Version 1
Data collection points and timetable for phase 3 Version 1
Recruitment and consent of resident participants Version 1
Example of case vignette Version 1
Distress protocol Version 1

References:

1. Moriarty, J., Rutter, D., Ross, P. D. S., & Holmes, P. (2012). End of life for people with dementia living in care homes. London: Social Care Institute for Excellence.
2. Mitchell, S. L., Kiely, D. K., & Hamel, M. B. (2004). Dying with advanced dementia in the nursing home. [Comparative Study
Research Support, Non-U.S. Gov't
Research Support, U.S. Gov't, P.H.S.]. *Archives of Internal Medicine, 164*(3), 321-326.
3. Mitchell, S. L., Teno, J. M., Kiely, D. K., Shaffer, M. L., Jones, R. N., Prigerson, H. G., et al. (2009). The clinical course of advanced dementia. [Multicenter Study
Research Support, N.I.H., Extramural]. *New England Journal of Medicine, 361*(16), 1529-1538.
4. Goodman, C., Evans, C., Wilcock, J., Froggatt, K., Drennan, V., Sampson, E., et al. (2010). End of life care for community dwelling older people with dementia: an integrated review. [Research Support, Non-U.S. Gov't Review]. *International Journal of Geriatric Psychiatry, 25*(4), 329-337.
5. Sampson, E. L., Ritchie, C. W., Lai, R., Raven, P. W., & Blanchard, M. R. (2005). A systematic review of the scientific evidence for the efficacy of a palliative care approach in advanced dementia. [Review]. *International Psychogeriatrics, 17*(1), 31-40.
6. Bebbington, A., Darton, R., & Netten, A. (2001). *Care Homes for Older people: Volume 2 admissions, needs and outcomes. The 1995/96 National Longitudinal Survey of Publicly-Funded Admissions*: Personal Social Services Research Unit, University of Kent.
7. Luff, R., Ferreira, Z., & Meyer, J. (2011). Care homes. London: NIHR School for Social Care Research.
8. Davies, S., Goodman, C., Bunn, F., Victor, C., Dickinson, A., Iliffe, S., et al. (2011). A systematic review of integrated working between care homes and health care services. *BMC Health Services Research, 11*(1), 320.
9. Gage, H., Dickinson, A., Victor, C., Williams, P., Cheynel, J., Davies, S. L., et al. (2012). Integrated working between residential care homes and primary care: a survey of care homes in England. *BMC Geriatrics, 12*(1), 71.
10. Hearn, J., & Higginson, I. (1999). Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. *Quality in Health Care, 8*(4), 219-227.
11. Froggatt, K., Davies, S., & Meyer, J. (2009). Research and development in care homes: setting the scene. In K. Froggatt, S. Davies, & M. J. (Eds.), *Understanding Care Homes: A Research and Development Perspective* (pp. 9-22). London: Jessica Kingsley Publishers.
12. Higginson, I. J., & McCarthy, M. (1993). Validity of the support team assessment schedule: do staffs' ratings reflect those made by patients or their families? *Palliative Medicine, 7*(3), 219-228.
13. Aminoff, B. Z., Purits, E., Noy, S., & Adunsky, A. (2004). Measuring the suffering of end-stage dementia: reliability and validity of the Mini-Suffering State Examination. [Validation Studies]. *Archives of Gerontology and Geriatrics, 38*(2), 123-130.
14. Mental Capacity Act (2005). (Vol. Chapter 9). London: HMSO.
15. Gysels, M., Evans, C. J., Lewis, P., Speck, P., Benalia, H., Preston, N. J., et al. (2013). MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research. *Palliative Medicine*.
16. Scott, S., Jones, L., Blanchard, M., & Sampson, E. (2011). Study protocol: The behaviour and pain in dementia study (BePAID). *BMC Geriatrics, 11*(1), 61.

Appendix H. Coffee morning advertisement

Coffee morning poster_Version 1_06082013

The Palliative care Outcome Scale for residents with dementia: POS-Dem study

An intervention for people with dementia living in care homes

We would like to invite you to a coffee morning to tell you about our study and invite you to take part

The purpose of the POS-Dem study is to develop an intervention to improve symptom management and quality of life for residents with dementia.

In order to develop the intervention we would like to invite people living in residential care homes who have a diagnosis of dementia or have some cognitive difficulties to take part in the study. We would also like to invite family members or friends of residents with dementia or cognitive impairment.

If you are interested in this study and would like to find out more about it, please come to our coffee morning. Members of the research team will be available to discuss the project in more detail and written information of the study will be provided.

Date and time:
Venue:

For more information please do not hesitate to contact:

Clare Ellis-Smith (pictured above) on 020 78485434 or alexandra.c.ellis-smith@kcl.ac.uk

This study forms part of Project BuildCARE, led by King's College London and Cicely Saunders Institute, London UK. Project BuildCARE is about Building Capacity, Access, Rights and Empowerment for patients to improve the palliative care patients receive. Project BuildCARE is supported by Atlantic Philanthropies.

Cicely Saunders International

KING'S HEALTH PARTNERS

BuildCARE

KING'S College LONDON

University of London

Appendix I. Examples of participant information sheets from each data collection phase

Document Title: Participant information sheet for unpaid carers phase 2 focus groups (Version 4 31/03/2014)

The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes

Unpaid carer participant information sheet- phase 2 focus group

---

Background to the research

You are being invited to take part in a research study. Before you decide, we would like you to understand why the research is being done and how it would involve you. Please take time to read this information sheet very carefully. We will talk through this information with you and answer any questions you might have. Please ask if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. The following information might help you decide whether you want to join the study.

What is palliative care? The aim of palliative care is to achieve the best quality of life for patients and their families. This is achieved through the treatment of

pain and other distressing symptoms. Palliative care takes an approach to address all symptoms and problems that people with an illness might be experiencing.

What is the purpose of the study? The purpose of the study is to develop an assessment questionnaire called *POS-Dem*. This will be specifically for residents with memory loss. This questionnaire will help care home staff identify symptoms and problems. It will also help care home staff work with doctors and nurses to treat symptoms quickly and address any problems.

What is *The Palliative care Outcome Scale for Dementia (POS-Dem)?*

The Palliative care Outcome Scale (POS) is a measure that is already being widely used. It is a questionnaire designed to identify and assess palliative care problems and symptoms. We are adapting this questionnaire for people with cognitive problems (such as memory problems, communication difficulties or problems learning new things) to cater more specifically for their needs. POS-Dem is a simple questionnaire routinely filled in by care home staff for each resident that they look after. The questionnaire identifies possible problems that residents such as your relative or friend

might be experiencing. It should help care home staff identify problems such as pain or low mood. Care home staff can then use this assessment to work with GPs and district nurses to make sure that symptoms are treated quickly.

Why have I been chosen to take part? When developing an assessment questionnaire such as POS-Dem it is important to gain the views of people who have a good understanding of what is important. We therefore need your views in order to understand which questions should be included. We are asking you based on your experience as a carer and your knowledge of what your relative or friend may consider important. You have been invited as you consider yourself a relative or friend of a resident with cognitive difficulties or memory problems.

What's involved?

What will happen to me if I take part? If you agree to take part, we would like you to participate in a discussion group with other relatives or friends of people with memory difficulties. We will ask the group questions and then ask the group members to discuss these questions. The questions will be about what you

consider to be important quality of life concerns and what you would like to see gained from an assessment questionnaire such as POS-Dem. We would also like to understand how POS-Dem should be used in care to improve quality of life. We may ask you to participate in another discussion group later in the study. The discussion group is likely to take about one and a half hours. We will record the discussion so that we do not miss anything important.

Choosing to take part

We hope that you will be able to take part because it is important for us to understand relatives' and friends' views. This is so that we can develop POS-Dem to detect aspects of care that are important to residents as well as relatives and friends. However, we recognise that it may not be possible for you to participate at this point in time. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do withdraw from the study, we may still use the information you have provided up to the point of your withdrawal as once your information is combined with other information it is very difficult to withdraw your contribution.

What will happen to the information obtained and care provided?

What will happen to the way that care is provided? This research will not affect your standard of care or the care of any person related to you in anyway. It will not change your or their care options, or any relationships you have with any staff or researchers.

Will anyone else know about my involvement in the study? Other people taking part in the discussion groups will obviously be aware of your involvement and what you share. We are, of course, not able to guarantee that they will treat your information confidentially. Your name will be used on the recordings but we will treat all the information that you share confidentially. All information will be presented in an anonymous form which will not identify individuals.

Unless you object, we will write to your GP to advise him/her that you are participating in this study.

There may be an unlikely event when we will have to break confidentiality. This will only occur when we believe somebody may be at risk, and we need to act

on this information in order to ensure their safety and wellbeing. In this instance, we will only use the relevant information and pass it on a strictly need-to-know basis. This is a very unlikely and we would discuss this with you before sharing any of your information.

Some other questions and answers

Do I have to take part? No. It is entirely up to you to decide whether or not to take part. This will not affect the care that your relative/friend or you receive.

Who is organising and funding this study? This study is funded by Cicely Saunders International and the Atlantic Philanthropies. It is part of a PhD research project based at King's College London.

What will happen to the results of the study? The findings of this study will published in scientific journals and PhD thesis. An edited summary of the results, written in non-technical language, may be sent to policy makers, staff, and individual users of services, their caregivers and charities. If you wish we can send you a copy of the results.

Need more information or want to talk to someone else?

More information: All research is looked at by an independent committee of people called a Research Ethics Committee, to protect your interests. This study has been reviewed by the National Research Ethics Service Committee London – South East and it has been given a favourable opinion. However, if you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Contact details are included at the end of this information sheet.

Concerns: If you remain unhappy and wish to complain formally, you can do so by contacting the research team on 020 78485434 or 020 78485565. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

Become involved: We welcome any suggestions that you have to improve this research. We are happy to share the findings of the research with you regardless of whether you participate or not. Thank you very much for taking the time to read this sheet. Please contact us for more information.

Researcher contact details

Name Clare Ellis-Smith (pictured below)
Telephone 020 78485434
Email alexandra.c.ellis-smith@kcl.ac.uk

King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, 6 Bessemer Road, Denmark Hill, London SE5 9PJ; Telephone: +44 (0)20 7848 5565 Fax: +44 (0)20 7848 5517. www.csi.kcl.ac.uk

Thank you

Unpaid carer participant information sheet_phase2 focus group_Version 4_310314

Document Title: Care home staff participant information sheet for phase 2 cognitive interviews (Version 2 01/11/2013)

The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes

Care home staff participant information sheet – phase 2 cognitive interviews

Background to the research

We would like to invite you to take part in a research study. Before you decide, we would like you to understand why the research is being done and how it would involve you. Please take time to read this information sheet very carefully. Please ask if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. The following information might help you decide whether you want to join the study.

What is the purpose of the study? The purpose of this study is to develop a measurement tool to help care home staff working in residential care homes identify palliative care problems (such as pain or low mood) and work with district nurses and GPs to enable prompt treatment of symptoms and improve overall quality of life.

Why have I been chosen to take part? When developing a measurement tool it is important to understand how people using it understand and interpret the questions and guidance. We have invited you to take part as you work in a care home and therefore might be using this tool as part of your care.

What's involved?

We would like you to participate in an interview about how you read, understand and interpret the measurement tool and the accompanying guidance. In particular, we would like you to go through each item on the tool and think out loud while you are doing so. This will help us understand how you interpret the questions. We will ask you questions about your thoughts in order to better understand your interpretation of the tool. We will record the interviews with your permission.

Choosing to take part

We hope you will be able to participate because it is important that we know this measurement tool is correctly understood and interpreted by people like you. However we recognise that it may not be possible for you to participate at this point of time. If you do decide to take part you are still free to withdraw at any time and without giving reason. If you do withdraw from the study, we may still use the information you have provided up to the point of your withdrawal as once your information is combined with other information it is very difficult to withdraw your contribution.

What will happen to the information I supply?

Your name may be used on the recordings however all transcripts will have no identifiable information and all information will be treated confidentially. All information will be presented anonymously in a form which will not identify individuals.

The only occasion where we may have to break confidentiality is when we learn about a vulnerable adult being at risk. We will then need to act on this information in order to ensure their safety and wellbeing. In this instance, we will only use the relevant information and share it on a strictly need-to-know basis.

Some other questions and answers

Do I have to take part? No. It is entirely up to you to decide whether or not to take part. If you choose not to take part, this will not impact on any relations that you have with the research team or your work in the care home.

Who is organising and funding this study? This study is funded by Cicely Saunders International and the Atlantic Philanthropies. It is part of a PhD research project based at King's College London.

What will happen to the results of the study? The findings of this study will published in scientific journals. A lay summary of the results for wider dissemination may be sent to policy makers, staff, and individual users of services, their caregivers and charities. If you wish we can send you a copy of the results.

Need more information or want to talk to someone else?

More information: All research is looked at by an independent committee of people called a Research Ethics Committee, to protect your interests. This study has been reviewed by the National Research Ethics Service Committee London – South East and it has been given a favourable opinion. However, if you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. Contact details are included at the end of this information sheet.

Concerns: If you remain unhappy and wish to complain formally, you can do so by contacting the research team on 020 78485434 or 020 78485565. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

Become involved: We welcome any suggestions that you have to improve this research. We are happy to share the findings of the research with you regardless of whether you participate or not. Thank you very much for taking the time to read this sheet. Please contact us for more information.

Researcher contact details

Name Clare Ellis-Smith **Telephone** 020 78485434

Email alexandra.c.ellis-smith@kcl.ac.uk

King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, 6 Bessemer Road, Denmark Hill, London SE5 9PJ
Fax: +44 (0)20 7848 5517. www.csi.kcl.ac.uk

Thank you

Document Title: Brief participant information sheet for residents (Version 4 15/03/2015)

The Palliative care Outcome Scale for Dementia – Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Why are we doing this project?

We want to develop a new type of assessment questionnaire (POS-DemA) to help those in charge of your care identify problems that people with memory difficulties may be experiencing. We believe that its use may reduce common symptoms and problems.

What is POS-DemA?

POS-DemA is a simple questionnaire routinely filled in by care home staff for each resident they look after. The questionnaire consists of possible problems that residents like you might be experiencing. It will help care home staff identify problems such as pain or low mood for people like you. Care home staff can then use this information to work with GPs and district nurses to make sure that symptoms are treated quickly and effectively.

What does taking part involve?

We will ask the care home staff, doctors and nurses looking after you to use POS-DemA for twelve weeks. In order to understand better how POS-DemA works, we will read your care home notes. For the same reason, we will also ask the care home staff to fill in similar questionnaires about you before and after the twelve-week period. On occasions over the twelve weeks, we may observe care home staff discussing your care with a doctor or nurse. You will not have to do anything and do not need to leave the care home to take part in this study.

Are there any risks?

We do not expect there to be any risks to taking part. POS-DemA is designed to help identify any problems that you might have so that these can be treated promptly. We do not yet know how accurate it is yet.

Any questions?

Please turn over this page for the contact details of who to contact if you would like to discuss this further.

Contact details:

Name: Clare Ellis-Smith

Telephone: 020 78485434

Address: King's College London, Cicely Saunders Institute, Bessemer Road, London, SE5 9PJ

Thank you

Document Title: Participant information sheet for residents who have capacity to consent (Version 4 15/03/2015)

The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Participant information sheet

Background to the research

You are being invited to take part in a research study. Before you decide, we would like you to understand why the research is being done and how it would involve you. Please take time to read this information sheet very carefully. We will talk through this information with you and answer any questions you might have. Please ask if anything is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. The following information might help you decide whether you want to join the study.

What is palliative care? The aim of palliative care is to achieve the best quality of life for patients and their families. This is achieved through the treatment of pain and other distressing symptoms. Palliative care takes an approach to address all symptoms and problems that people with an illness might be experiencing.

What is the purpose of the study? The purpose of the study is to develop an assessment questionnaire called *POS-DemA*. This will be used with residents with memory loss. This questionnaire will help care home staff identify symptoms and problems. It will also help care home staff work with doctors and nurses to treat symptoms quickly and address any problems.

What is *The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA)?* The Palliative care Outcome Scale (POS) is a measure that is already being widely used. It is a questionnaire designed to identify and assess the type and level of palliative care problems. We are adapting this questionnaire for people with memory problems. POS-DemA is a simple questionnaire routinely filled in by care home staff for each resident they look after. The questionnaire will identify possible problems that residents like you might be experiencing. It should help care home staff identify problems such as pain or low mood for people like

you. Care home staff can then use this assessment to work with GPs and district nurses to make sure that symptoms are treated quickly.

Why have I been chosen to take part? You have been chosen to take part as we think that POS-DemA might help people like you. We would therefore like to understand how it works by introducing it to your care. The care home staff looking after you have suggested that you may wish to take part.

What's involved?

What will happen to me if I take part? If you decide to take part, we will ask the care home staff to fill in the POS-DemA questionnaire on a regular basis for twelve weeks. This will involve the staff answering questions on a form about possible problems or symptoms that you might have. POS-DemA will also have an additional brief questionnaire where staff will be asked about the usefulness of POS-DemA in providing your care. It will not require any active involvement from you. It might mean that care home staff ask you about you about any problems that you might have. They may then use this information to work with your doctor or nurses in treating you to make you more comfortable.

Before and after the new POS-DemA questionnaire is used with you, we will ask care home staff to complete other similar questionnaires about you. This will help us understand whether POS-DemA has helped you. We will read your care home records for the same reason. Finally, on occasions over the twelve weeks, we may observe care home staff and a doctor or nurse when they meet to discuss your health. This is all intended to help us understand how POS-DemA works.

If you agree to take part, we will ask you to sign a consent form. This will be to show that you have understood what the study is about and that you are happy to take part. We will discuss this consent process with you to make sure you have understood what is involved before you sign the form. To make sure that your needs are looked after throughout the study, we will also ask someone close to you (or another independent person) to advise us whether you should take part. You

will not have to do anything and you will not have to leave the care home to participate in this study.

What are the possible disadvantages and risks of taking part? We do not expect any significant risks. As we do not yet know how accurate POS-DemA is at detecting problems, it may be that your problems are not identified accurately. POS-DemA will NOT replace the clinical judgement of the people looking after you. Rather, it should help identify potential problems.

What are the possible benefits of taking part? The POS-DemA questionnaire is aimed at helping you achieve the best quality of life possible through prompt treatment of symptoms and problems. We do not yet know if it works as we are still in the process of developing it. This is why we need to do this study.

What will happen to my treatment and the information obtained?

What will happen to my treatment? This research will not affect your standard of care you or the care of any person related to you in anyway. It will not affect your or their care options, or any relationships you have with any staff or researchers.

Will anyone else know about my involvement in the study? All information about you will be treated confidentially. We will follow ethical and legal guidelines to make sure this happens. Your information will be anonymised which means that you or anyone else will NOT be able to be identified. The information obtained will be stored in a safe place. Any identifiable information will be kept separately. We may keep the information collected for use in future studies but all this information will be completely anonymous. We will only do this if you agree.

As this study involves the care home staff, your GP and community nurses, it is likely that they will be aware of your participation in this study. However, unless

you object, we will write to your GP to advise him or her that you have decided to take part.

There may be an unlikely event when we will have to break confidentiality. This will only occur when we believe you or somebody else may be at risk. We would then need to act on this information in order to ensure your or their safety and wellbeing. In this instance, we will only use the relevant information and pass it on a strictly need-to-know basis. We would discuss this with you before sharing any of your information.

Some other questions and answers

Do I have to take part? No. It is entirely up to you to decide whether or not to take part. Even if you agree to participate you are free to withdraw at any time, without giving a reason. If you do withdraw from the study, we may still use the information collected up to the point of your withdrawal as once your information is combined with other information it is very difficult to withdraw your contribution.

Who is organising and funding this study? This study is funded by the Cicely Saunders International and the Atlantic Philanthropies. It is part of a PhD research project based at King's College London.

What will happen to the results of the study? The findings of this study will published in scientific journals and PhD thesis. An edited summary of the results in non-technical language may be sent to policy makers, staff, and individual users of services, their caregivers and charities. If you wish we can send you a copy of the results.

Need more information or want to talk to someone else?

More information: All research is looked at by an independent committee of people called a Research Ethics Committee, to protect your interests. This study

has been reviewed by the National Research Ethics Service Committee London – London South East and it has been given a favourable opinion. However, if you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Contact details are included at the end of this information sheet.

Concerns: If you remain unhappy and wish to complain formally, you can do so by contacting the research team on 020 78485434 or 020 78485565. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

Become involved: We welcome any suggestions that you have to improve this research. We are happy to share the findings of the research with you regardless of whether you participate or not. Thank you very much for taking the time to read this sheet. Please contact us for more information.

Researcher contact details

Name Clare Ellis-Smith (pictured below) **Telephone** 020 78485434

Email alexandra.c.ellis-smith@kcl.ac.uk

King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, 6 Bessemer Road, Denmark Hill, London SE5 9PJ;
Telephone: +44 (0)20 7848 5565
Fax: +44 (0)20 7848 5517. www.csi.kcl.ac.uk

Thank you

Document Title: Consultee information sheet (Version 4 15/03/2015)

The Palliative care Outcome Scale for Dementia – Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Information for consultees

Introduction

We would like to invite ..... to participate in this research project. As it is a project aimed at people who have dementia or cognitive impairment (such as difficulties remembering, communicating or learning new information), we believe that your relative or friend may not be able to decide for himself/herself whether to participate in this research. Even if they are able to decide, we are aware that due to the nature of memory difficulties, they may lose this capacity over the duration of the project.

To help decide whether they should participate in the study, we would like to ask your opinion whether or not they would want to be involved. We would like to ask you to consider what you know of their wishes and their feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. They should take precedence.

If you decide that they would have no objection to taking part, we will ask you to read and sign the consultee declaration. We will then give you a copy to keep. If you have any concerns and feel that they should be withdrawn from the study at a later stage, please let us know. Before you sign, please ask if there is anything that is not clear or if you would like more information.

If you decide that they would not wish to take part in this study, it will not affect the care they receive in any way. If you are unsure about taking the role of consultee you may seek independent advice. You are under no obligation to undertake this role and if you feel that there is somebody better placed to do so, please let us know.

The following is information is the same that would have been (or has been) provided to your relative or friend.

Background to the research

What is palliative care? The aim of palliative care is to achieve the best quality of life for patients and their families. This is achieved through the treatment of pain and other distressing symptoms. Palliative care takes an approach to address all symptoms and problems that people with an illness might be experiencing.

What is the purpose of the study? The purpose of the study is to develop an assessment questionnaire called *POS-DemA*. This will be used with residents with memory loss. This questionnaire will help care home staff identify symptoms and problems. It will also help care home staff work with doctors and nurses to treat symptoms quickly and address any problems.

What is *The Palliative care Outcome Scale for Dementia (POS-DemA)?* The Palliative care Outcome Scale (POS) is a measure that is already being widely used. It is a questionnaire designed to identify and assess the type and level of palliative care problems. We are adapting this questionnaire for people with memory problems. POS-DemA is a simple questionnaire routinely filled in by care home staff for each resident they look after. The questionnaire will identify possible problems that residents like your relative/friend might be experiencing. It should help care home staff identify problems such as pain or low mood for people like your relative or friend. Care home staff can then use this assessment to work with GPs and district nurses to make sure that symptoms are treated quickly.

Why has my relative/friend been chosen to take part? They have been chosen to take part as we think that POS-DemA might help people like them. We would therefore like to understand how it works by introducing it to their care. The care home staff looking after them have suggested that they may wish to take part.

What's involved?

What will happen to them if they take part? If you decide that they should take part, we will ask the care home staff to fill in the POS-DemA questionnaire on a regular basis for twelve weeks. This will involve care home staff answering questions on a form about possible problems or symptoms that your relative or friend might have. POS-DemA will also have an additional brief questionnaire where staff will be asked about the usefulness of POS-DemA in providing your relative's or friend's care. It will not require any active involvement from your relative or friend. It might mean that care home staff ask them

questions about any problems they have. They may then use this information to work with doctors and nurses in treating your relative or friend to make him/her more comfortable. Before and after the new POS-DemA questionnaire is used with your relative or friend, we will ask care home staff to complete other similar measures about them. This will help us understand whether POS-DemA has helped your relative or friend. We will read their care home records for the same reason. Finally, on occasions over the twelve weeks, we may observe care home staff and a doctor or nurse when they meet to discuss your relative's or friend's health. This is all intended to help us understand better how POS-DemA works.

What are the possible disadvantages and risks of taking part? We do not expect any significant risks. As we do not yet know how accurate POS-DemA may be at detecting problems, it may be that problems are not identified accurately. The results of the questionnaire will NOT replace the clinical judgement of the people looking after them. Rather, it should help identify potential problems.

What are the possible benefits of taking part? The POS-DemA questionnaire is aimed at helping your relative or friend achieve the best quality of life possible through prompt treatment of symptoms and problems. We do not yet know if it works as we are still in the process of developing it. This is why we need to do this study.

What will happen to their treatment and the information obtained?

What will happen to their treatment? This research will not affect their standard of care they or the care of any person related to them in any way. It will not affect their care options, or any relationships that they or you may have with any of the staff or researchers.

Will anyone else know about their involvement in the study? All information about them will be treated confidentially and we will follow ethical and legal practice guidelines to make sure this happens. Their information will be anonymised which means that they or you or anyone else will NOT be able to be identified. The information obtained will be stored in a safe place. Any identifiable information will be kept separately. We may keep the information collected for use in future studies but all this information will be kept completely anonymous. We will only do this if they and/or you agree.

As this study involves the care home staff, GP and community nurses, it is likely that they will be aware of your relative's/friend's participation in this study. However, unless you or they object, we will write to their GP to advise him or her that your relative/friend is taking part.

There may be one unlikely event where we will have to break confidentiality. This will only occur when we believe that your relative/friend or somebody else may be at risk. We would need to act on this information in order to ensure their safety and wellbeing. In this instance, we will only use the relevant information and provide it on a strictly need-to-know basis. This is very unlikely.

Some other questions and answers

Do they have to take part? No and they can be withdrawn from the study at any time without giving a reason. If they do withdraw, we may still use the information collected up to the point of withdrawal as once the information is combined with others it is very difficult to withdraw their contribution.

Who is organising and funding this study? This study is funded by the Cicely Saunders Institute and Atlantic Philanthropies. It is part of a PhD research project based at King's College London.

What will happen to the results of the study? The findings of the study will be published in scientific journals and PhD thesis. An edited summary of the results in non-technical language may be sent to policy makers, staff, and individual users of services, their caregivers and charities. If you wish we can send you a copy of the results.

Need more information or want to talk to someone else?

More information: All research is looked at by an independent committee of people called a Research Ethics Committee, to protect your interests. This study has been reviewed by the National Research Ethics Service Committee London – London South East and it has been given a favourable opinion. However, if you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. Contact details are included at the end of this information sheet.

Concerns: If you remain unhappy and wish to complain formally, you can do so by contacting the research team on 020 78485434 or 020 78485565. Any complaint about the way you or your relative/friend have been dealt with during the study or any possible harm they might suffer will be addressed.

Become involved: We welcome any suggestions that you have to improve this research. We are happy to share the findings of the research with you regardless of whether you relative/friend participates. Thank you very much for taking the time to read this sheet. Please contact us for more information.

Researcher contact details

Name Clare Ellis-Smith **Telephone** 020 78485434

Email alexandra.c.ellis-smith@kcl.ac.uk

King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, 6 Bessemer Road, Denmark Hill, London, SE5 9PJ

Telephone: 020 78485434 Fax: 020 78485517 www.csi.kcl.ac.uk

Thank you

Appendix J. Examples of participant consent and consultee declaration forms

Document Title: Participant consent form for unpaid carers (Version 2 15/03/2015)

The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Consent form for unpaid carers

Participant Name:

Title of Research Study: The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Consent for: phase two/ phase three (circle)

		Initials
1	I confirm that I have read and understood the information leaflet dated ..... for the above research study and I have received an explanation of the nature, purpose, and duration of the research study and what my involvement will be.	☐
2	I have had time to consider whether to take part in this research study. My questions have been answered satisfactorily and I have received a copy of the Participant Information Leaflet.	☐
3	I agree for my General Practitioner, Dr ..... of ..... surgery to be informed that I am taking part in this research study.	Yes/No
4	I agree to take part in a focus group or interview and agree that this may be recorded.	☐

Participant consent form for unpaid carers_Version 2_15032015

5	I confirm that the information collected about me can be used for teaching and educational purposes as well as future research projects if it is anonymised before use.	☐
6	I agree to be contacted during the time of the study	☐
7	I agree to take part in the above research study.	☐

……	……	……
Name of Participant (in block letters)	Date	Signature
……	……	……
Name of Person taking consent	Date	Signature

King's College London, Cicely Saunders Institute,
Department of Palliative Care, Policy and Rehabilitation,
6 Bessemer Road, Denmark Hill, London SE5 9PJ; Telephone: +44 (0)20 7848 5565; Fax: +44 (0)20 7848 5517.
www.csi.kcl.ac.uk

Thank you

Document Title: Participant consent form for residents who have capacity to consent (Version 2 15/03/2015)

The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Consent form for resident participants

Resident Name:

Title of Research Study: The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

		Initials
1	I confirm that I have read and understood the information leaflet dated ..... for the above research study and I have received an explanation of the nature, purpose, duration, and forseeable effects and risks of the research study and what my involvement will be.	☐
2	I have had time to consider whether to take part in this research study. My questions have been answered satisfactorily and I have received a copy of the Participant Information Leaflet.	☐
3	I understand that my General Practitioner and other health professionals looking after me may be aware that I am taking part in this research study.	☐
4	I agree for my General Practitioner, Dr ..... to be informed that I am taking part in this research study.	Yes/No

5	I understand that sections of any care home notes may be looked at by the researcher/s where it is relevant to the research. I give my permission for this to happen.	☐
6	I agree to the care home staff, General Practitioner(s) and district nurse(s) using POS-DemA when providing care for me for a period of twelve weeks.	☐
6	I agree that additional measures and questionnaires will be completed by care home staff looking after me as part of the research study.	☐
7	I agree that meetings about me between care home staff and my general practitioner and/or district nurse may be observed for the purposes of this research. I give my permission for this to happen.	☐
7	I confirm that the information collected about me can be used for teaching and educational purposes as well as future research projects if it is anonymised before use.	☐
8	I agree to somebody close to me or an independent professional being approached prior to the study commencing to get their approval for my participation.	☐
9	I agree to take about in the above research study.	☐

.....	.....	.....
Name of Patient (in block letters)	Date	Signature
.....	.....	.....
Name of Person taking consent	Date	Signature

King's College London, Cicely Saunders Institute,
Department of Palliative Care, Policy and Rehabilitation,
6 Bessemer Road, Denmark Hill, London SE5 9PJ; Telephone: +44 (0)20 7848 5565; Fax: +44 (0)20 7848 5517.
www.csi.kcl.ac.uk

Thank you

Document Title: Consultee declaration form (Version 2 15/03/2015)

The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

Consultee declaration form

Resident participant name:

Consultee name:

Title of Research Study: The Palliative care Outcome Scale for Dementia - Assessment (POS-DemA): an intervention for people with dementia living in care homes

		Initials
1	I, ..., have been consulted about .....'s participation in this research project. I have read and fully understood the information leaflet dated ..... and have had the opportunity to ask questions.	☐
2	In my opinion, he/she would have no objection to taking part in this study.	☐
3	I understand that I can request that he/she is withdrawn from the study at any time, without giving any reason. I understand that it may not, however, be possible to withdraw information already collected.	☐
4	I understand that his/her General Practitioner and other health professionals looking after him/her may be aware that he/she is taking part in this research study.	☐

5	I agree for his/her General Practitioner, Dr ..... to be informed that I am taking part in this research study.	Yes/No
5	I understand that sections of any care home notes maybe looked at by the researcher/s where it is relevant to the research. I give my permission for this to happen.	☐
6	I agree to the care home staff, General Practitioner(s) and district nurse(s) using POS-DemA when providing care for him/her for a period of twelve weeks.	☐
7	I agree that additional measures and questionnaires will be completed by care home staff looking after him/her as part of the research study.	☐
8	I agree that meetings about him/her between care home staff and general practitioner and/or district nurse may be observed for the purposes of this research. I give my permission for this to happen.	☐
9	I confirm that the information collected about him/her can be used for teaching and educational purposes as well as future research projects if it is anonymised before use.	☐

……	……	……
Name of Consultee (in block letters)	Date	Signature
Relationship to participant ……		
Name of participant ……		
……	……	……
Name of Person taking consent	Date	Signature

King's College London, Cicely Saunders Institute,
Department of Palliative Care, Policy and Rehabilitation,
6 Bessemer Road, Denmark Hill, London SE5 9PJ; Telephone: +44 (0)20 7848 5565; Fax: +44 (0)20 7848 5517.
www.csi.kcl.ac.uk

Thank you

Appendix K. Letter of approach to personal consultee

Faculty of Life Sciences & Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson OBE
BMedSci BMBS PhD FMedSci FRCP FFPHM
Head of Department
Professor Lynne Turner-Stokes
DM FRCP
Herbert Dunhill
Chair of Rehabilitation

Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ
Tel: +44 (0)20 7848 5516
Fax: +44 (0)20 7848 5517
www.kcl.ac.uk/palliative

KING'S College LONDON

Document Title: Personal Consultee letter of approach (version 1 24/03/2015)

Dear

We are a team of health professionals (doctors, nurses, therapists) and researchers from King's College London working together on a research project. The aim of the project is to develop an assessment tool to support the assessment and management of symptoms and problems in people with memory problems, or dementia. We are working with three residential care homes in this project, including the one your relative or person you know is living in.

We have developed the assessment tool called Palliative care Outcome Scale for Dementia – Assessment (POS-DemA). We would now like to test whether and how the assessment tool works to support care and health provision for care home residents.

We are inviting your relative or person you know well to take part in this research study. The care home manager has identified them as someone who may be suitable to take part. The care home manager is sending you this letter on our behalf. They have not shared your details with us and we will not contact you without your permission.

We realise that your relative or person you know may find it difficult to make a decision about whether to participate in this study. However, it is very important that we work with people like them to understand whether the assessment tool we are developing can benefit people like them. Their participation in this study will therefore make a very valuable contribution.

We would be very grateful for your opinion as to whether you think …… would wish to take part in this research. We are not asking you to provide a personal view on the research topic or consent on behalf of the person. We are asking you to consider, to the best of your knowledge, whether they would not object to taking part in this study, and would not cause any undue distress by taking part.

Faculty of Life Sciences & Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson OBE
BMedSci BMBS PhD FMedSci FRCP FFPHM
Head of Department
Professor Lynne Turner-Stokes
DM FRCP
Herbert Dunhill
Chair of Rehabilitation

Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ
Tel: +44 (0)20 7848 5516
Fax: +44 (0)20 7848 5517
www.kcl.ac.uk/palliative

KING'S College LONDON

Taking part in the study would mean that the care home staff use the assessment tool with your relative or person you know for a period of 12 weeks. The care home staff will complete the assessment tool and it will not require any active participation from your relative or person you know. The enclosed information leaflet provides more detail about the project and what taking part involves.

If you are able to give an opinion or would like more information, please contact Clare Ellis-Smith by phone on 020 78485434, by email at alexandra.c.ellis-smith@kcl.ac.uk, or complete the attached reply slip and return in the enclosed stamped and addressed envelope. We will send you another letter within the next two weeks as a reminder.

If you do not respond within the next three weeks, we will assume that you do not wish to provide an opinion. We will then ask a professional consultee to provide an opinion as to whether your relative or person you know should take part in the study. A professional consultee is somebody who knows about the research project but is independent from the research project.

Thank you in anticipation for considering this request. We look forward to hearing from you.

Yours sincerely

Clare Ellis-Smith
Cicely Saunders International PhD Training Fellow

Dr Catherine Evans
Clinical Lecturer and Clinical Nurse Specialist in Palliative Care

Enc: Consultee Information Sheet
Stamped addressed envelope

Faculty of Life Sciences & Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson OBE
BMedSci BMBS PhD FMedSci FRCP FFPHM
Head of Department
Professor Lynne Turner-Stokes
DM FRCP
Herbert Dunhill
Chair of Rehabilitation

Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ
Tel: +44 (0)20 7848 5516
Fax: +44 (0)20 7848 5517
www.kcl.ac.uk/palliative

KING'S College LONDON

Name of care home resident ……

Name of care home ……

Your name ……

Relationship to care home resident ……

I would like to be contacted to provide advice as to whether the above resident should take part in the research study:

The Palliative care Outcome Scale for Dementia – Assessment (POS-DemA): an intervention for people with dementia living in residential care homes

My contact details are:

Telephone: ……

Email ……

Address ……

……

……

By responding to this letter you are agreeing to be contacted by the research team.

If you do not reply, we will assume that you do not wish to be consulted and we will approach a professional consultee to advice on participation for your relative or person you know.

Please return to: Clare Ellis-Smith, PhD Training Fellow, King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, Bessemer Road, Denmark Hill, London, SE5 9PJ

Appendix L. Topic guides

Topic guide for phase 2 focus groups with unpaid carers

Research objectives

To explore:

- Content validity, including comprehensiveness of POS-Dem
- Processes and structures: how POS-Dem is likely to work in practice to improve resident outcomes

1. Introduction

Welcome

We are developing an assessment tool to be used with residents with dementia in order to improve identification of problems and aid communication between professionals. In order to do this, we need your input.

How the focus group works:

- *Recording*
- *Confidentiality*
- *Timing*
- *We have a lot to get through, I apologise in advance if I have to interrupt and move to the next topic*

- *You do not have to answer any questions that you do not feel comfortable with*
- *Participation is entirely voluntary, and you can withdraw at any time.*
- *Should you wish to leave the focus group, and support available both during and after the discussion*
- *We would welcome any feedback or suggestions on how it could be improved, or if anything has not been clear.*

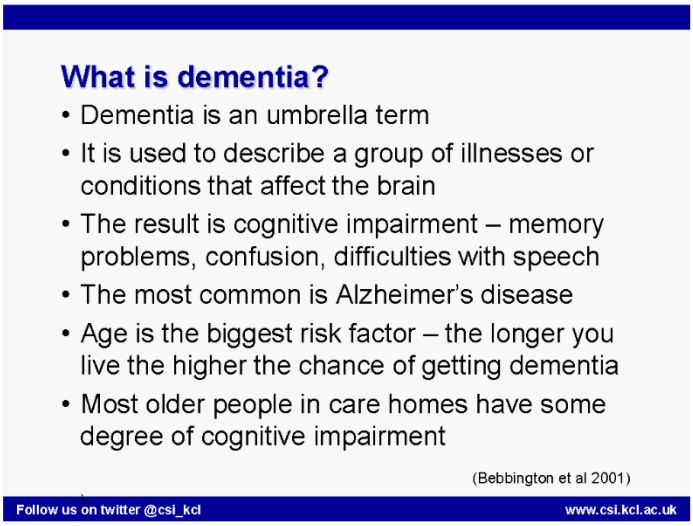
Introductions – Clare Ellis-Smith and 2nd researcher and members of the group (name, relationship to resident, how long has your relative/friend been a resident)

[5 minutes]

2. Background

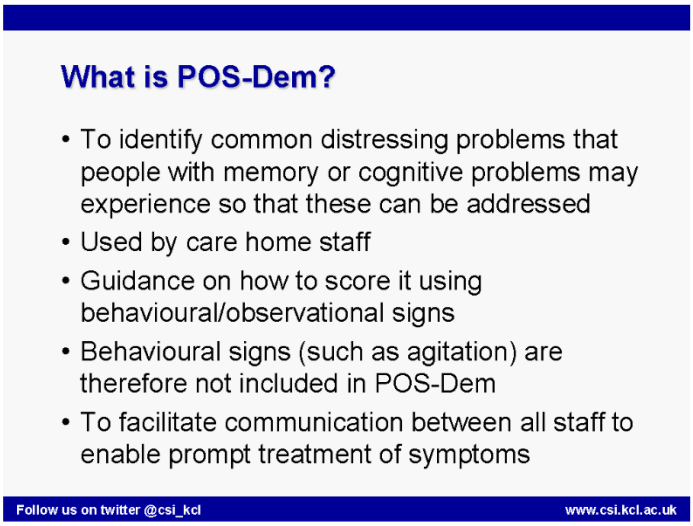
Aim: To introduce the purpose of the research and for the purpose of the focus groups

What is dementia?

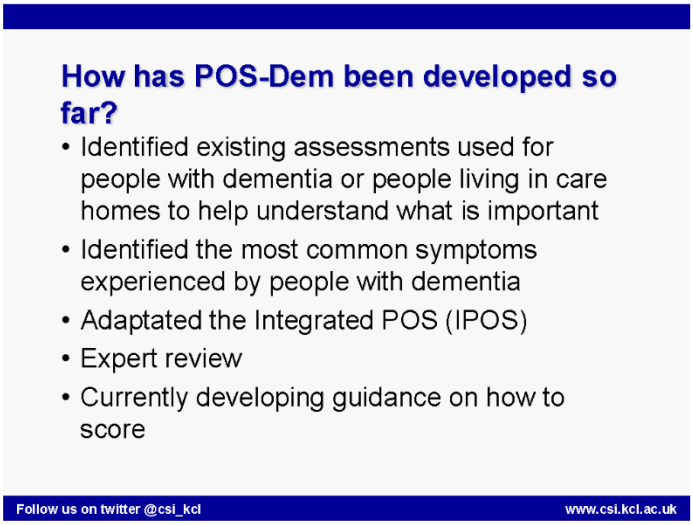


What is palliative care?

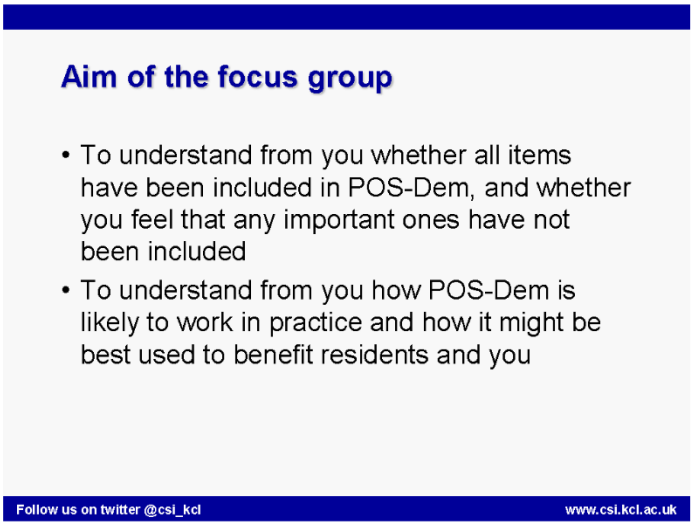
What is POS-Dem?



How has POS-Dem been developed so far?



Aim of the focus group:



[Questions, comments]

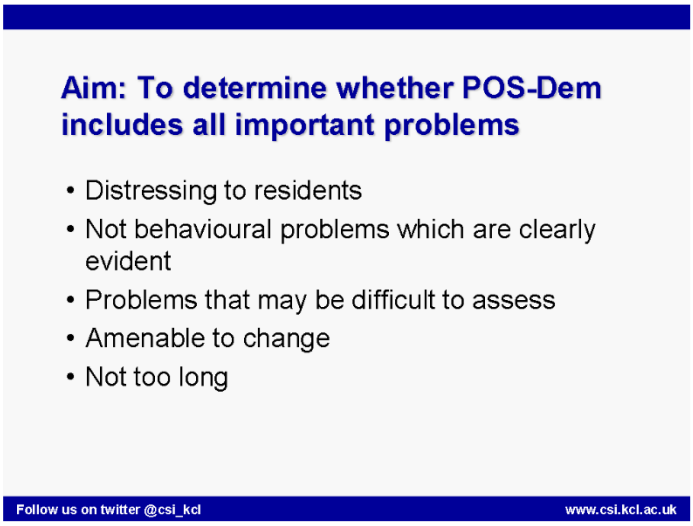
[5 minutes]

3. Content validity of POS-Dem, in particular comprehensiveness

Aim: To determine unpaid carers' opinions as to whether the items in POS-Dem cover all the important domains

PowerPoint slide: Aim: To determine whether POS-Dem includes all important domains

- Problems that are underlying and not a result of another problems
- Problems that are amenable to change



Handout: POS-Dem

Q. What do you think of the items currently included? Are they relevant, important, and amenable to change?

Q. Do you think there is anything important missing from POS-Dem?
Prompts: Do you think that all distressing problems that your relative/friend might experience are there? Do you think that relative and friends' needs are represented?

Q. Do you think there are any items or problems that should not be included?

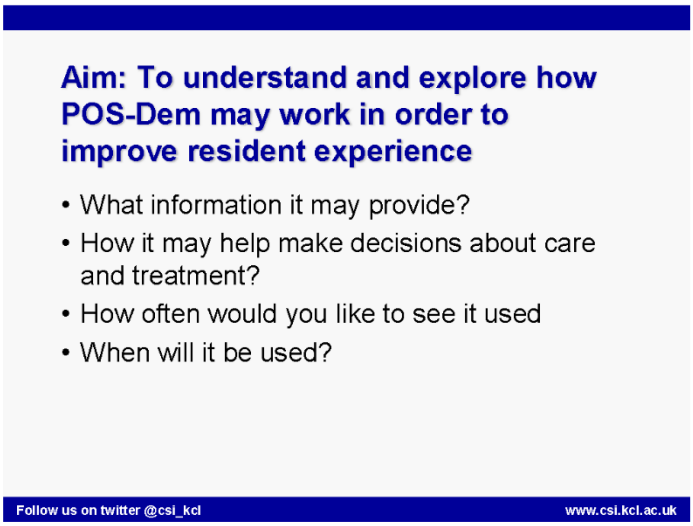
Q. Any other comments?

[15-20 minutes]

4. Structure and processes – understanding how POS-Dem is likely to work in practice, and how best it should be utilised to improve resident outcomes

Aim: To understand and explore how POS-Dem may work in order to improve resident outcomes

PowerPoint slide: Aim: To understand and explore how POS-Dem may work in order to improve resident outcomes



Now I would like to understand a little more how you feel that this tool should work in care. Here is an example:

Handout: Vignette one

Mrs Hazel Matthews and her husband, Mr James Matthews

Hazel is a 72 year old lady with moderate Alzheimer's disease. She has been living in the residential care home for nine months and moved there when her husband had a stroke and was no longer able to look after her. Mr Matthews has made a good recovery and visits Hazel regularly but is no longer able to care for Hazel at home.

Hazel needs support for most of personal care needs. She walks independently but sometimes needs some help to stand up from a chair. Hazel sometimes has problems finding the right word which can cause her to become frustrated.

Since moving into the care home, Hazel has settled well. She engages in all her personal care needs although requires some encouragement to eat her meals. She is, however, reluctant to take part in any of the activities in the care home and prefers to sit by herself frequently isolating herself in her own bedroom.

Hazel is at times tearful but no-one knows why. At these times, her communication tends to worsen causing her to become visibly more distressed. Later, when asked, Mrs Matthews does not appear to recall her tearfulness and seems surprised that she might have been.

Q. How do you think using POS-Dem could help or support Hazel and her husband?
Prompts:

- How might it be used to support the couple?
- What changes to care might be expected as a result?
- How might this improve Hazel and her husband's situation?
- How might it be used to help communication? (between care home staff, health care staff, families and people with dementia)
- How might information be communicated between all people involved in care?
- What would happen with the results?
- How might changes to care and healthcare provided come about?

Q. How do you think POS-Dem could be best used to help Hazel and her husband?
Prompts: Who (observers, raters, senior staff?) How? Who should have access to guidance? How will information be shared between observers and raters? How would you share your observations and concerns with staff who might complete it?

Q. Do you seen any challenges to POS-Dem being used?
Prompts: Time, difficulty completing, communication barriers?

[20-25 minutes]

Now I would like to understand more about *when* POS-Dem should be used:

Handout: vignette two

Mr and Mrs Matthews three months later:

Mr Matthews, however, has suddenly become unwell and had a two-week hospital admission. He is now much frailer and not able to visit frequently. Without close family nearby, he finds it difficult to get to the care home.

Hazel has become markedly more withdrawn. She isolates herself frequently and, for the first time, has started to resist some of the care provided. While she has always been a small eater and required some encouragement to eat, she now seems to have lost her appetite entirely. She is losing weight and staff are worried that she may be becoming under-nourished and at risk of dehydration.

At times Hazel becomes quite agitated, wandering around the care home. At these times she is very distressed but has problems explaining herself. As a result, she becomes more distressed and agitated.

Q. When do you think POS-Dem should be used?

Prompts:

- Regularly as part of routine care – if so, how regularly; what is the benefit of this, what are the challenges to this; how would staff remember to use this at such intervals?
- Only at unstable, deteriorating times? If so, how will you decided; what is the benefit of this, what are the challenges to this?

Q. What time period should it refer to? How long should the rating period be?

[15-20 minutes]

Total time: 60 – 75 minutes

References:

- Bebbington, A., Darton, R., & Netten, A. (2001). *Care Homes for Older people: Volume 2 admissions, needs and outcomes. The 1995/96 National Longitudinal Survey of Publicly-Funded Admissions*: Personal Social Services Research Unit, University of Kent.
- Hearn, J., & Higginson, I. (1999). Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. *Quality in Health Care*, 8, 219-227.
- Higginson, I.J., Koffman, J., Hopkins, P., Prentice, W., Burman, R., Leonard, S., et al. (2013). Development and evaluation of the feasibility and effects on staff, patients, and families of a new tool, the Psychosocial Assessment and Communication Evaluation (PACE), to improve communication and palliative care in intensive care and during clinical uncertainty. *BMC Medicine*, 11.

Acknowledgements

BuildCARE aims to create a 'sea change' in the way palliative and end-of-life care is regarded, implemented and prioritised internationally.

BuildCARE is a four-year project, supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies.
We thank all collaborators & advisors including service-users.

BuildCARE members:

Chief Investigator: Irene J Higginson.
Project Co-coordinator: Barbara A Daveson.

Emma Bennett, Dr Barbara Daveson, Susanne de Wolf-Linder, Dr Mendy Dzingina, Clare Ellis –Smith, Dr Catherine Evans, Dr Taja Ferguson, Dr Lesley Henson, Prof Irene J Higginson, Dr Pauline Kane, Dr Paul McCrone, Dr Regina McQuillan, Dr Diane Meier, Dr Sean Morrison, Dr Fliss Murtagh, Prof Charles Normand, Caty Pannell, Ana Reison, Dr Karen Ryan, Melinda Smith, Katy Tobin, Rowena Vohora, Dr Gao Wei

www.kcl.ac.uk/palliative
http://www.cicelysaundersfoundation.org/research/project-buildcare

Follow us on twitter @csi_kcl www.csi.kcl.ac.uk

Topic guide for phase 2 focus groups with paid professionals

Research objectives

To explore:

- Content validity, including comprehensiveness of POS-Dem
- Processes and structures: how POS-Dem is likely to work in practice to improve resident outcomes

1. Introduction

Welcome

We are developing an assessment tool to be used with residents with dementia in order to improve identification of problems and aid communication between professionals. In order to do this, we need your input.

How the focus group works:

- *Recording*
- *Confidentiality*
- *We have a lot to get through, I apologise in advance if I have to interrupt and move to the next topic*

- *Agree signal if wish to leave and support available both during and after the discussion*
- *We would welcome any feedback or suggestions on how it could be improved, or if anything has not been clear.*

Introductions – Clare Ellis-Smith and 2nd researcher and members of the group (name, job role)

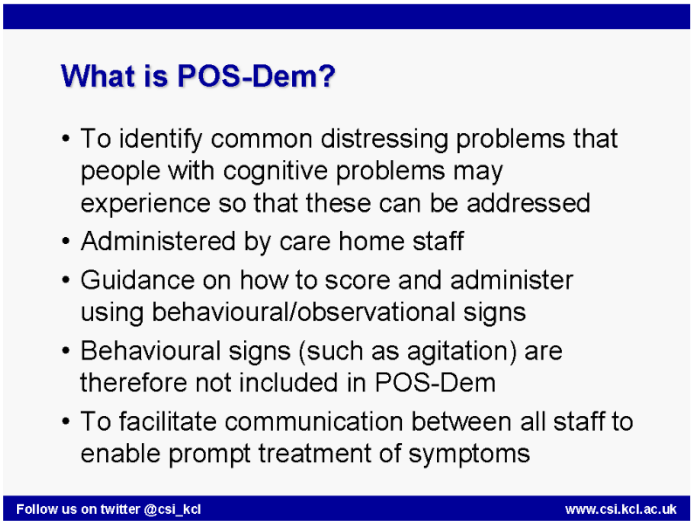
[5 minutes]

2. Background

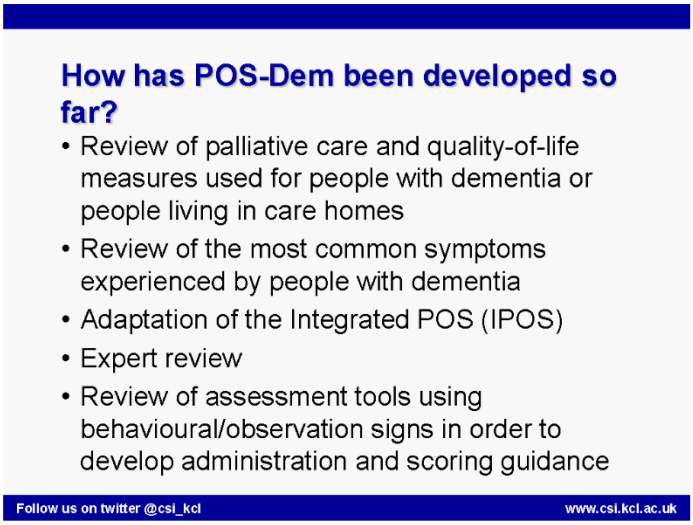
Aim: To introduce the purpose of the research and for the purpose of the focus groups

What is palliative care?

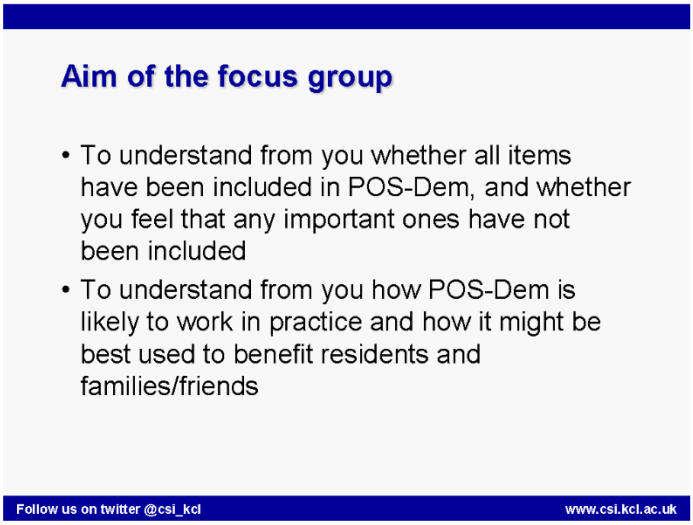
What is POS-Dem?



How has POS-Dem been developed so far?



Aim of the focus group:



[Questions, comments]

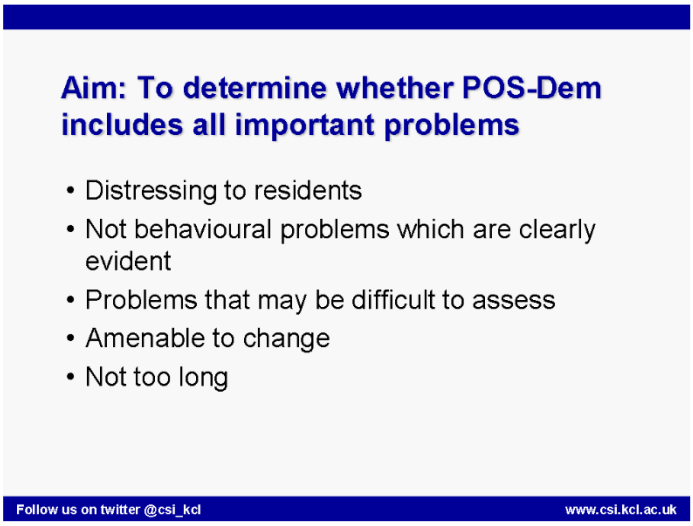
[5 minutes]

3. Content validity of POS-Dem, in particular comprehensiveness

Aim: To determine whether professionals' opinions as to whether the items in POS-Dem cover all the important domains

PowerPoint slide: Aim: To determine whether POS-Dem includes all important domains

- Problems that are underlying and not a result of another problems
- Problems that are amenable to change



Handout: POS-Dem

Q. What do you think about the length of POS-Dem?

Q. What do you think of the items currently included? Are they relevant, important, and amenable to change?
Prompt: Do you think there is anything there that should not be there?

Q. Do you think there is anything important missing from POS-Dem?
Prompt: Is this underlying and amenable to change?

Q. Do you think there are any items or problems that should not be included?

Q. Would it be useful to have information on stage of dementia to inform assessment?

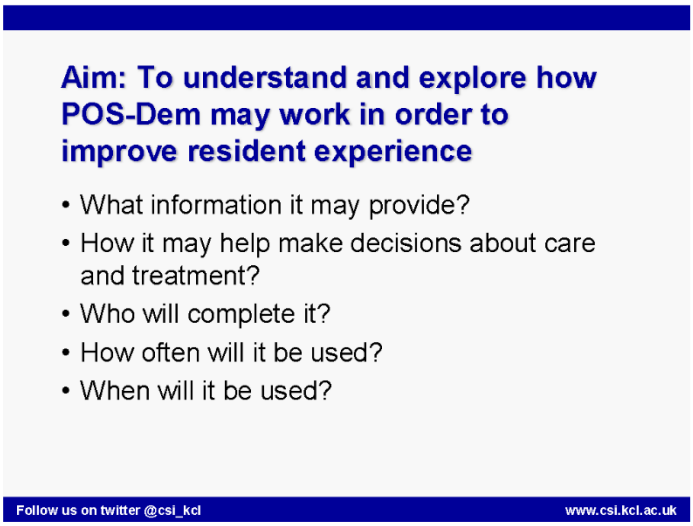
Q. Any other comments?

[15-20 minutes]

4. Structure and processes – understanding how POS-Dem is likely to work in practice, and how best it should be utilised to improve resident outcomes

Aim: To understand and explore how POS-Dem may work in order to improve resident outcomes

PowerPoint slide: Aim: To understand and explore how POS-Dem may work in order to improve resident outcomes



Now I would like to understand a little more how you feel that this tool should work in care. Here is an example:

Handout: Vignette one

Mrs Hazel Matthews and her husband, Mr James Matthews

Hazel is a 72 year old lady with moderate Alzheimer's disease. She has been living in the residential care home for nine months and moved there when her husband had a stroke and was no longer able to look after her. Mr Matthews has made a good recovery and visits Hazel regularly but is no longer able to care for Hazel at home.

Hazel needs support for most of personal care needs. She walks independently but sometimes needs some help to stand up from a chair. Hazel sometimes has problems finding the right word which can cause her to become frustrated.

Since moving into the care home, Hazel has settled well. She engages in all her personal care needs although requires some encouragement to eat her meals. She is, however, reluctant to take part in any of the activities in the care home and prefers to sit by herself frequently isolating herself in her own bedroom.

Hazel is at times tearful but no-one knows why. At these times, her communication tends to worsen causing her to become visibly more distressed. Later, when asked, Mrs Matthews does not appear to recall her tearfulness and seems surprised that she might have been.

Q. How do you think using POS-Dem could help or support Hazel and her husband?
Prompts:

- How might it be used to support the couple?
- What changes to care might be expected as a result?
- How might this improve Hazel and her husband's situation?
- How might it be used to help communication? (between care home staff, health care staff, families and people with dementia)
- How might information be communicated between all people involved in care?
- What would happen with the results?
- How might changes to care and healthcare provided come about?

Q. How do you think POS-Dem could be best used to help Hazel and her husband?
Prompts: Who (observers, raters, senior staff?) How? Who should have access to guidance? How will information be shared between observers and raters?

Q. What are the challenges to using POS-Dem?
Prompts: Time, difficulty completing, communication barriers?

Q. What about existing measures or tools that you use? How would POS-Dem fit with the tools already in use?
Prompts: Do you think POS-Dem can complement these, if not, how can it be used so that work is not duplicated?

[20-25 minutes]

Now I would like to understand more about *when* POS-Dem should be used:

Handout: vignette two

Mr and Mrs Matthews three months later:

Mr Matthews, however, has suddenly become unwell and had a two-week hospital admission. He is now much frailer and not able to visit frequently. Without close family nearby, he finds it difficult to get to the care home.

Hazel has become markedly more withdrawn. She isolates herself frequently and, for the first time, has started to resist some of the care provided. While she has always been a small eater and required some encouragement to eat, she now seems to have lost her appetite entirely. She is losing weight and staff are worried that she may be becoming under-nourished and at risk of dehydration.

At times Hazel becomes quite agitated, wandering around the care home. At these times she is very distressed but has problems explaining herself. As a result, she becomes more distressed and agitated.

Q. When do you think POS-Dem should be used?

Prompts:

- Regularly as part of routine care – if so, how regularly; what is the benefit of this, what are the challenges to this; how would staff remember to use this at such intervals?
- Only at unstable, deteriorating times? If so, how will you decided; what is the benefit of this, what are the challenges to this?

Q. What time period should it refer to? How long should the rating period be?

Q. What is the best format? Would it be of benefit to develop an electronic version with the potential of linking to other systems in the future?

[15-20 minutes]

Total time: 60 – 75 minutes

References:

- Hearn, J., & Higginson, I. (1999). Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. Palliative Care Core Audit Project Advisory Group. *Quality in Health Care*, 8, 219-227.
- Higginson, I.J., Koffman, J., Hopkins, P., Prentice, W., Burman, R., Leonard, S., et al. (2013). Development and evaluation of the feasibility and effects on staff, patients, and families of a new tool, the Psychosocial Assessment and Communication Evaluation (PACE), to improve communication and palliative care in intensive care and during clinical uncertainty. *BMC Medicine*, 11.

Follow us on twitter @csi_kcl www.csi.kcl.ac.uk

Acknowledgements

BuildCARE aims to create a 'sea change' in the way palliative and end-of-life care is regarded, implemented and prioritised internationally.

BuildCARE is a four-year project, supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies.

We thank all collaborators & advisors including service-users.

BuildCARE members:

Chief Investigator: Irene J Higginson.
Project Co-coordinator: Barbara A Daveson.

Emma Bennett, Dr Barbara Daveson, Susanne de Wolf-Linder, Dr Mendy Dzingina, Clare Ellis –Smith, Dr Catherine Evans, Dr Taja Ferguson, Dr Lesley Henson, Prof Irene J Higginson, Dr Pauline Kane, Dr Paul McCrone, Dr Regina McQuillan, Dr Diane Meier, Dr Sean Morrison, Dr Fliss Murtagh, Prof Charles Normand, Caty Pannell, Ana Reison, Dr Karen Ryan, Melinda Smith, Katy Tobin, Rowena Vohora, Dr Gao Wei

www.kcl.ac.uk/palliative
http://www.cicelysaundersfoundation.org/research/project-buildcare

Follow us on twitter @csi_kcl www.csi.kcl.ac.uk

School of Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson
BMedSci BMBS FFPHM PhD FRCP
Head of Department
Professor Lynne Turner-Stokes
DM FRCP
Herbert Dunhill
Chair of Rehabilitation

Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ
Tel: +44 (0)20 7848 5516
Fax: +44 (0)20 7848 5517
www.kcl.ac.uk/palliative

KING'S College LONDON

Topic Guide

The Palliative care Outcome Scale for Dementia (POS-Dem): an intervention for people with dementia living in residential care homes (Phase 2 cognitive interviews)

Objective:

- To explore the cognitive processes used by respondents when reading and interpreting POS-Dem *Instructions*
- To explore the cognitive processes used by respondents when reading, interpreting and responding to items on the POS-Dem assessment tool using *Help and guidelines to use POS-Dem*

- *Introduction:*

  - Study purpose, confidentiality, able to stop at any time, decline questions I'm going to show you an assessment tool and I want you to read the instructions and then read & answer the questions one at a time
  - We will stop and talk about each paragraph and question before moving onto the next
  - Please try to 'think out loud' as you read and answer the questions (*DEMONSTRATE*)
  - I will also ask you some more specific things as we go along

  - Apologies if the questions get repetitive

  - We have a lot to get through and I do not want to take up too much of your time, I apologise in advance if I have to interrupt and move on

  - In this study we are less interested in your answers to the questions, but *how you think about answering* the questions – what you think the question means, and the things you were thinking about when you chose your answer.

  - You can tell me *any* thoughts or views you might have about any of the sections or questions

---------- START RECORDING ----------

Purpose, Background and Instructions

- *General*
  - What were you thinking about when you read this paragraph?
- *Comprehension*
  - **What does this paragraph mean to you, in your own words?**
  - **How easy or difficult was it to understand this paragraph?**
  - If problem, how would you change this paragraph?

For severity and frequency ratings/ symptom indicators:

- What do these paragraphs mean to you

- *Judgement*

For severity and frequency ratings/ symptom indicators:

- How do you think this information should be used?

POS-Dem questions

- *General:*
  - What were you thinking about when you answered that question?
  - I noticed you hesitated before giving your answer – what were you thinking about then?
- *Comprehension:* ***What does the respondent believe the question to be asking?***
  - What does the question mean to you, in your own words?
  - What does the word XXXXXX mean to you? (if certain words are thought to be problematic)
  - **How easy or difficult was it to understand this question?**
  - (If problem) How would you change this question?

  If applicable:

  - **How easy or difficult is it to understand the symptom indicators?**
  - What does the word XXXXX mean to you?

- *Retrieval:* ***Could they recall the information required by the question? Was the time frame suitable?***
  - How well could you remember the information required when answering this question?
  - **Was it easy or difficult to think about the past [week] when answering this question?**
  - Would there be a different time period that would be easier to understand?

- *Judgement:* ***Is the respondent able to make an evaluation based on the information recalled?***
  - What were you thinking about when you answered this question?
  - How did you arrive at your answer to that question?
  - What information did you use to answer your question?
  - Was that easy or hard to arrive at your answer? Why do you say that?
  - **How sure are you of the answer to this question?**
  - What other information might you obtain to help you answer this question?

- *Response:* ***Is the respondent able to map their internally generated answer to a response option?***
  - How did you choose your answer to this question?
  - **Was it hard or easy to select an answer from the options given?**
  - Did all options make sense for this question?

- *Other:*

  About POS-Dem

  - Are there any topics/questions that you would leave out of this questionnaire?
  - Are there any topics/questions that you would add to this questionnaire?
  - Is there anything else you would like to say about the questionnaire as a whole? Inappropriate questions/ Irrelevant questions?
  - Was is easy or difficult to use symptom indicators?
  - Was it easy or difficult to use the information about severity and frequency?
  - How should symptom indicators be presented in to support use of POS-Dem?

  General questions about use in routine care

  - What would make this questionnaire useful in routine care?
  - What might be the reasons that you would use it?
  - What would prevent you from using it?

---------- THANKS + STOP RECORDING ----------

---------- COMPLETION OF DEMOGRAPHICS FORM ----------

Topic guide for phase three unpaid carer focus groups

Research objectives:

- To explore the potential benefit of POS-DemA
- To explore the acceptability of POS-DemA to family members

1. Introduction

Thank you for taking part in this focus group. The purpose of the focus group is to understand your perspective and your experience of how the assessment tool that we have developed (POS-DemA) may be supporting the care provided to your relative.

Palliative care: The aim of palliative care is to achieve best quality of life for residents and their families. This is achieved through prompt treatment of distressing symptoms and concerns. Palliative care can benefit anyone experiencing symptoms and concerns at any stage of an illness, including frail older people.

POS-DemA is an assessment that has been developed from the well-established POS (Palliative care Outcome Scale). POS has been developed for other patient groups. We adapted POS to reflect the symptoms and concerns experienced by older people living in care homes. Adapting it involved earlier work with care staff, health care staff and family members to understand important symptoms. We have then tested with care staff to ensure good comprehension and clarity.

Your participation is entirely voluntary (you can withdraw at any time) and you do not have to answer questions that you do not feel comfortable with.

- *Recording*
- *Confidentiality – we will anonymise transcripts, please respect each other's confidentiality*
- *Timing*
- *I know your time is valuable and I do not want keep you too long. For this reason I will be keeping an eye on the clock to make sure that there is time to cover all the points. I apologise in advance if I need to move onto the next question*
- *I would welcome any feedback or suggestions on how the work that we are doing could be improved, or if anything has been unclear*
- *Feedback of results*

[10 minutes]

Introductions: *Please state who you are. It would be helpful if you could say a little bit about how long your relative has been in the care home and your relationship*

Aim: To explore the potential benefit of using POS-DemA and the underlying mechanisms of action

Q: What has been your experience of the care staff using (or not using) POS-DemA over the past month?

Prompts: are you aware that it has been used, have you had access to this information, do you think that it has been used

Q: Thinking about your family member, do you think (or have you seen) there is any potential benefit in POS-DemA being used as part of their care?

If so, please explain

Q: Thinking about your family member, do you think (or have you noticed) there is any risk of harm to them from POS-Dem being used as part of their care?

If so, please explain

Q: From your perspective as a family member, do you think POS-DemA may have any impact or effect on you. If so, please explain

Prompts: any potential benefits to you, support communication, any concerns

Q: Would you like to see such a measure implemented in the routine care of your family member? Please explain.

Q: Do you have any concerns about such a measure being implemented in the routine care of your family member. Please explain.

Aim: To explore the acceptability of POS-DemA to family members

Q: Do you think that the items on POS-DemA address symptoms and concerns important to your family member and to you?

Q: Are there any questions that you are concerned about or that you find distressing?

Q: Do you have any comments or concerns about the measure overall?

Q: Is there anything else that you would like to say that we have not spoken about?

Topic guide for carer focus groups

Research objectives:

- To explore the feasibility and acceptability of using POS-Dem in routine are of residents
- To explore the implementation requirements of POS-DemA
- To explore the potential benefit of POS-DemA

Introduction

Thank you for agreeing to take part in this discussion group. The purpose of the discussion is to understand your experience of using POS-DemA with the residents participating in the study.

In particular, we would like to get your perspective on whether POS-DemA plays a role in supporting the care you provide, whether there are any problems or challenges to using POS-DemA, and whether you think any changes are required to help using POS-DemA. Your participation is entirely voluntary (you can withdraw at any time) and you do not have to answer questions that you do not feel comfortable with.

- *Recording*
- *Confidentiality*
- *Timing*
- *Feedback and suggestions*

[5 minutes]

Feasibility and acceptability

Aim: To explore the care staff's perceptions of the feasibility of using POS-DemA in the routine care of residents with dementia, and the acceptability of POS-Dem

Q: What has been your experience of using POS-DemA?

Prompts: Have you used it? How often have you used it? When have you used it? Has anything stopped you using it?

Q: Have there been in challenges or problems using POS-DemA?

Prompts: time, understanding the questions, understanding how to use it, remembering to use it, practical problems (e.g. access to copies)

Q: Has anything helped you use POS-DemA?

Prompts: Quick to complete, easy to use, instruction manual

Q: Are there any changes you would make to POS-DemA that would make it easier to use?

Q: Do you think that the questions are relevant to the residents that you care for?

Prompts: any ones that are more useful, any that are less useful

Q: Are there any questions that you had problems answering?

Prompts: Difficult to know whether the residents has the problem? Access to information? Understanding the question?

Q: Was it easier or harder to use POS-Dem for different residents?

Prompts: severity of dementia, more symptoms, how well you know the residents

Q: Can you tell me what you think about potential value of information gained from POS-DemA compared to the time taken to use it?

[20 minutes]

Implementation requirements

Aim: To explore staff's perception of resources, training or support that may facilitate implementation of POS-DemA in routine care

Q: What support do you think is needed to use POS-DemA

Prompts: training, practical support from manager or senior staff, opportunity to ask questions

Q: What has been your experience of using the instruction manual?

Prompts: have you had access to it, have you read instruction manual, was it understandable and make sense, any challenges to reading the instruction manual

Q: What would help you to start using POS-DemA regularly for residents?

Prompts: Time from manager, training, getting feedback of the results, more resources

Q: How do you think this should be provided?

Prompts: training (face to face), video training, presentations, external facilitator

Q: Would you like a bit more support using POS-DemA? Could you explain.

[15 minutes]

Potential benefit of POS-DemA

Aim: To explore the potential benefit of using POS-DemA and the underlying mechanisms of action

Q: Do you think that POS-DemA has the potential to support care you provide? If so, could you explain.

Q: Could you explain whether or not POS-DemA supports assessment of residents with dementia?

Q: Could you explain whether or not any information is gained from using POS-DemA?

Prompts: do you learn anything new, or does it not provide any new information

Q: Could you explain whether the information gained from using POS-DemA can be used to inform the care that you provide? Could you explain further?

Q: Are there any more useful or less useful questions on POS-DemA?

Q: When and how frequently do you think POS-DemA should be used? Please explain.

Q: Do you think that POS-DemA can support communication? If so, with whom? How?

Q: What, if any, do you think the benefit to residents of using POS-DemA?

Q: What, if any, do you think the benefit to families of using POS-DemA?

Q: Do you think there are any risks of harm to residents of using POS-DemA?

Q: Do you think there are any risks of harm to families by using POS-DemA?

Q: What strategies would help you act on any resident problems that you identify?

Q: Do you have any other comments or thoughts about what we have spoken about?

[20 minutes]

Topic guide for phase three manager serial interviews

Research objectives:

- To explore the feasibility and acceptability of using POS-DemA in routine care of residents
- To explore the implementation requirements of POS-DemA
- To explore the potential benefit of POS-DemA

1. Introduction

Thank you for agreeing to be interviewed. The purpose of this interview is to review the experience of you and your staff when using POS-DemA with the residents participating in this study.

In particular, we want to get your perspective on whether or not POS-DemA is useful in supporting the care you provide to residents with dementia, whether there are any problems or challenges to staff using POS-DemA, and whether you think there are any changes that would help your staff to use POS-DemA better. Your participation is entirely voluntary (you can withdraw at any time) and you do not have to answer questions that you do not feel comfortable with.

- *Recording*
- *Confidentiality*
- *Timing*
- *I know your time is valuable and I do not want keep you too long. For this reason I will be keeping an eye on the clock to make sure that there is time to cover all the points. I apologise in advance if I need to move onto the next question*
- *I would welcome any feedback or suggestions on how the work that we are doing could be improved, or if anything has been unclear*

[5 minutes]

2. Feasibility and acceptability

Aim: To explore the managers' perceptions of the feasibility of the care home using POS-DemA in the routine care of residents with dementia, and the acceptability of POS-DemA to care staff

Q: What has been your experience of the care staff using (or not using) POS-DemA over the past month?

Prompts: staff feedback - spontaneous or through formal meetings?

Q: Have there been any barriers to your staff using POS-DemA over the past month?

Prompts: time, problems understanding or using POS-DemA, low staffing levels, lack of motivation

Q: Has anything particularly helped or supported staff using POS-DemA?

Prompts: Quick to complete, easy to use, training manual

Q: Are there any changes you would make to POS-DemA that would make it easier to use?

Q: Do you think that the questions on POS-DemA are relevant and pertinent to the care that your staff provide?

Q: Can you tell me more about the value of the information gained completing POS-DemA versus the time spent using it?

[20 minutes]

3. Implementation requirements

Aim: To explore the managers' perceptions of what resources, training, or support may facilitate implementation of POS-DemA into routine care

Q: What, if any, has been your role in using POS-DemA?

Prompts: prompts to use POS-DemA, providing guidance or support, monitoring

Q: How easy or difficult has it been to request that your staff use POS-DemA for the people that they keywork?

Prompts: Motivation, confidence, time issues, comprehension of purpose of POS-DemA, difficulties of using POS-DemA

Q: What do think might help staff use POS-DemA?

Prompts: additional training, feedback of results, more resources

Q: How do you think that this help would be best provided, and most easily accessible to staff?

Prompts: Training (face to face), video training, presentations, external (link) facilitator

Q: Would you like more support in helping your staff use POS-DemA? If yes, could you tell me a bit more?

[15 minutes]

4. <u>Potential benefit of POS-DemA</u>

Aim: To explore the potential benefit of using POS-DemA and the underlying mechanisms of action

Q: Do you think that using POS-DemA has the potential to support care provided?

Q: If so, could you explain how in your own words.

Q: Could you explain whether the information gained from using POS-DemA be used to inform care? If yes, could explain how. If no, could you explain why you think this is the case.

Q: If yes, how and which questions or areas in particular?

Q: When, and how frequently do you think that it is useful to use POS-DemA?

Q: When would you repeat a POS-DemA measurement?

Q: Do you think POS-DemA can support communication?

Prompts: with whom, how

Q: What, if any, do you think the benefit is to residents/ families to using POS-DemA?

Q: Do you think there are any risks of harm to residents/ families by using POS-DemA?

Q: What strategies do you think could be put in place to ensure that problems identified are acted upon?

Q: Do you have any other comments or thoughts about what we have spoken about?

[20 minutes]

Appendix M. Case note data extraction form

The Palliative care Outcome Scale for Dementia – Assessment (POS-DemA) study

Care Home Case Note Data Extraction Form

Resident Name	
Care home	
Date of data extraction	
Period of data extraction	From: To:

	Number of times completed in period	***Date(s) completed***	***Copy/ copies taken (please tick for each date)***
POS-DemA (please ensure that copies of all POS-DemA assessments with utility questionnaires are taken for analysis)			

Resident demographic data extraction: to be completed at first time point only			
	Medical diagnoses (please list)		Medications (please list all)
Age			
Diagnosis of dementia (yes/no)			
Type of dementia			
Gender			
Ethnicity			
Religion			
Dementia staging (from notes and staff)			
Receiving specialist palliative care (yes/no)			

Case Note Review Data Extraction Form_Version 1_24032015

	Date of care plan	Problems, symptoms, concerns identified (list)	Action plan
Care plan			

	Professional (e.g. GP, district nurse)	Date	Reason for consultation	Brief summary of content and action plan e.g. areas reviewed and plan of care
Professional review (review by health care professional)				

Ethnicity	
White – British	0
White – Irish	1
White – Other	2
White and Black Caribbean	3
White and Black African	4
White and Asian	5
Other Mixed	6
Indian	7
Pakistani	8
Bangladeshi	9
Other Asian	10
Black Caribbean	11
Black African	12
Black Other	13
Chinese	14
Other	15
Not Known	16

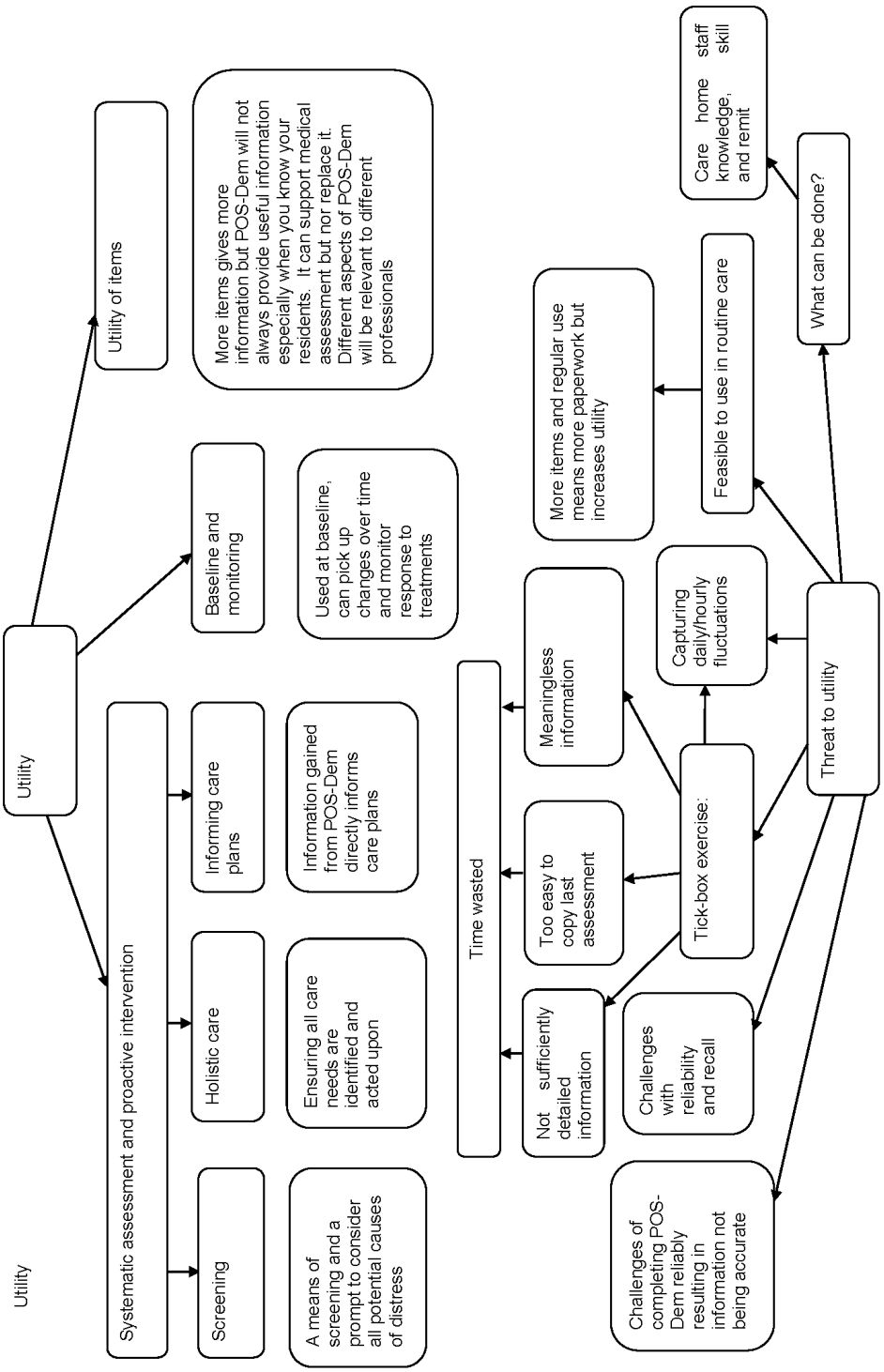
Religion	
Atheist	0
Buddhist	1
Christian – Catholic	2
Christian – C of E	3
Christian – Other / Not specified	4
Jewish	5
Hindu	6
Muslim	7
Sikh	8
Other	9
Not Known	10

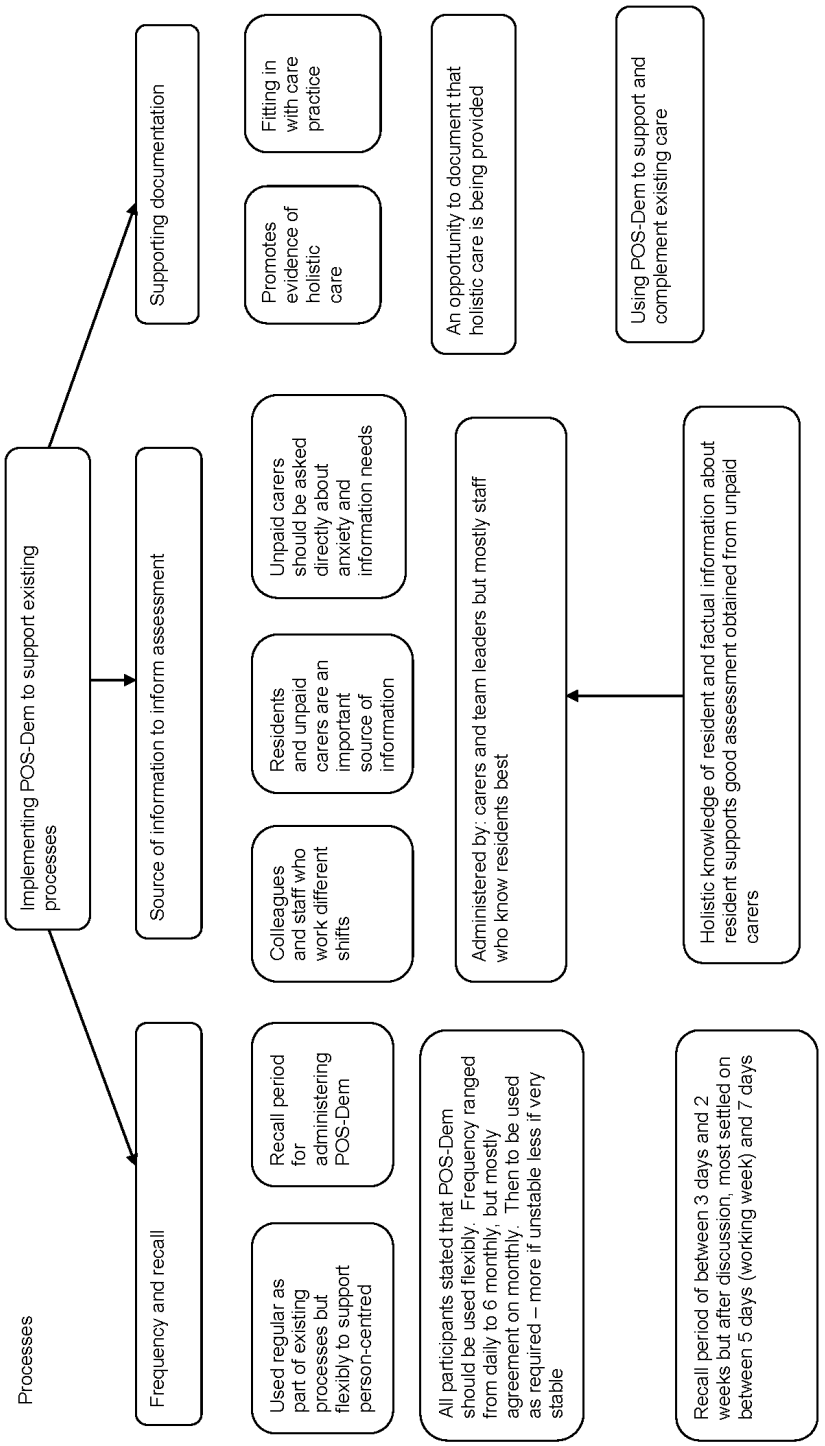
Dementia Staging - Functional Assessment Staging (FAST)		
1	Normal ageing	No deficits whatsoever
2	Possible mild cognitive impairment	Subjective functional deficit
3	Mild cognitive impairment	Objective functional deficit interferes with a person's most complex tasks
4	Mild dementia	Instrumental activities of daily living affected, such as bill paying, cooking, cleaning, traveling
5	Moderate dementia	Needs help selecting proper attire
6a	Moderately severe dementia	Needs help putting on clothes
6b	Moderately severe dementia	Needs help bathing
6c	Moderately severe dementia	Needs help toileting
6d	Moderately severe dementia	Urinary incontinence
6e	Moderately severe dementia	Fecal incontinence
7a	Severe dementia	Speaks 5-6 words a day
7b	Severe dementia	Speaks only 1 word clearly
7c	Severe dementia	Can no longer walk
7d	Severe dementia	Can no longer sit up
7e	Severe dementia	Can no longer smile
7f	Severe dementia	Can no longer hold head up

Reisberg, B. (1988). Functional assessment staging (FAST). ***Psychopharmacology Bulletin, 24*****(4), 653.**

For further information please contact Clare Ellis-Smith, alexandra.c.ellis-smith@kcl.ac.uk or 02078485434

Appendix N. Themes informing IPOS-Dem manual




Processes
Implementing POS-Dem to support existing processes
Frequency and recall
Used regular as part of existing processes but flexibly to support person-centred
Recall period for administering POS-Dem
All participants stated that POS-Dem should be used flexibly. Frequency ranged from daily to 6 monthly, but mostly agreement on monthly. Then to be used as required – more if unstable less if very stable
Recall period of between 3 days and 2 weeks but after discussion, most settled on between 5 days (working week) and 7 days
Source of information to inform assessment
Colleagues and staff who work different shifts
Residents and unpaid carers are an important source of information
Unpaid carers should be asked directly about anxiety and information needs
Administered by: carers and team leaders but mostly staff who know residents best
Holistic knowledge of resident and factual information about resident supports good assessment obtained from unpaid carers
Supporting documentation
Promotes evidence of holistic care
Fitting in with care practice
An opportunity to document that holistic care is being provided
Using POS-Dem to support and complement existing care

Appendix O. IPOS-Dem Versions

IPOS-Dem Version 1: Ready for development/pre-implementation phase focus groups/interviews

POS-Dem

www.pos-pal.org

Please write clearly

Name:.....

Date (dd/mm/yyyy):.....

Q1. What have been the person's main problems over [time period]?

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*
1.....					
	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
2.....					
	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
3.....					
	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

POS-Dem

www.pos-pal.org

Q2. Please tick one box that best describes how the person has been affected by each of the following symptoms despite medication in the last [time period]

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot Assess*
Pain	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Shortness of breath	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weakness or lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Nausea	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Vomiting	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor appetite	0 ☐	1☐	2 ☐	3 ☐	4 ☐	☐
Constipation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Mouth or dental problems	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weight loss	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Drowsiness	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor mobility	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Swallowing problems	0 ☐	1☐	2 ☐	3 ☐	4 ☐	☐
Skin breakdown	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Delusions	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Hallucinations	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please list any other symptoms and tick one box to who how you feel each of these symptoms have affected the person over the last [time period].

1.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
2.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
3.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

POS-Dem

www.pos-pal.org

Over the past [time period]

Q3 Has s/he been feeling anxious or worried?

No, not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Yes, always*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q4. Have any of his/her family or friends been anxious or worried about the person?

No, not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Yes, always*	*Not applicable*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q5. Do you think s/he has been feeling depressed?

No, not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Yes, always*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q6. Do you think that s/he is still able to enjoy things in life?

No, not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Yes, always*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q6. Do you think s/he has felt at peace?

Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q7. Has s/he been able to interact positively with others?

Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q8. Has his/her family had as much information as wanted?

Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*	*Not applicable*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q9. Does s/he have the opportunity to engage in enjoyable or pleasurable activities?

Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q10: Have any practical matters been addressed? [such as financial and personal]

Matters Addressed/	*Matters mostly addressed*	*Matters partly addressed*	*Matters hardly addressed*	*Matters not addressed*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Please specify all:

1.

2.

3.

If more than one, please rate worst problem that has not been addressed

---

IPOS-Dem Version 2: Ready for cognitive interviews round 1

The Palliative care Outcome Scale for Dementia

POS-Dem

An assessment tool to detect symptoms and problems in care home residents with dementia

Manual for use and assessment tool

POS-Dem

www.pos-pal.org

Purpose of POS-Dem

POS-Dem is an assessment tool to detect and manage symptoms and problems in care home residents. This includes residents with dementia or cognitive impairment. It is designed to be used by staff who provide direct care to residents. Any carer who knows the resident well can use POS-Dem. Clinical training or dementia training is not required. POS-Dem is a quick assessment tool. It can be used regularly as part of routine care.

We have developed POS-Dem because we know that it can be very difficult to detect symptoms and problems. It is particularly difficult in people with dementia.

Background

How did we develop POS-Dem?

POS-Dem is adapted from the Palliative care Outcome Scale (POS). Palliative care aims to relieve suffering and improve quality of life. This is achieved through good assessment and quick treatment of symptoms or problems. POS is used in palliative care settings throughout the world. These settings include hospital, hospices and community teams.

We changed POS so that it can be used with people with dementia in care homes. First, we used existing published knowledge to change POS. We then asked the opinions of experts. They were care home staff, families and friends of people with dementia, and doctors and nurses.

We developed POS-Dem by adding some dementia symptoms to the original POS. We also provided some help on how to assess symptoms. Based on what care home staff told us, we provided instructions on using POS-Dem in routine care.

POS-Dem

www.pos-pal.org

Instructions

Please read this section before using POS-Dem for the first time

How often should POS-Dem be used with each resident?

We recommend that you use POS-Dem when someone first moves into the care home. This is so that problems are identified as soon as possible. These can then be addressed in the care plan. We recommend that POS-Dem is then used monthly or at care plan reviews. You may also find it helpful to use POS-Dem if you notice a change in the person. This is so that you can detect any new symptoms or problems quickly. POS-Dem can be used as often as you find helpful.

Who should complete POS-Dem?

Any carer who provides regular and direct care should complete POS-Dem. Preferably, the carer who knows the person best.

How do I complete POS-Dem?

In all assessments it is best to ask the person directly. This is the best way to find out about problems or symptoms. You can do this as part of your normal care. For example, asking '*Does this hurt?*' when helping somebody stand up or wash.

People with dementia may not be able to tell you when they have a problem. You should complete POS-Dem based on your own observations of the person's behaviour. You should also have discussions with colleagues. Make sure you speak to colleagues who work different shifts. Read case notes especially if you do not have the opportunity to speak to colleagues. Ask family and friends for their opinions. Family and friends may also have their own concerns that need addressing.

We have provided signs of common symptoms to help you complete POS-Dem assessments. You can underline the signs you have observed. This will provide more information about your assessment. It could help explain your assessment to doctors or nurses.

POS-Dem

www.pos-pal.org

Should POS-Dem replace existing assessments?

POS-Dem should not replace other assessments. POS-Dem is NOT a risk assessment. It should NOT be used to replace risk assessments.

How can POS-Dem support the care that I provide?

POS-Dem is designed to help you detect symptoms and problems that may cause distress. POS-Dem can help you write care plans by identifying problems. By discussing POS-Dem with family and friends, you can also get their views and understand their concerns.

You can also use POS-Dem to work with doctors and nurses. You can show them the completed POS-Dem to help explain symptoms. The scores on POS-Dem can help you tell doctors and nurses how bad the symptoms are.

Used in this way, POS-Dem can support joined-up working between you, health professionals, family or friends, and residents.

IT IS VERY IMPORTANT THAT YOU TAKE ACTION WHEN YOU DETECT A PROBLEM. This action will depend on the problem or symptom. It will also depend on how bad the problem or symptom is. A higher score means a worse symptom or problem. This means that you may have to act **urgently**. You may wish to discuss higher scores with a senior member of staff. You may need to refer the person for an urgent review with the doctor for severe symptoms.

POS-Dem

www.pos-pal.org

How do I rate severity (questions 1-2)?

Not at all - no evidence of any symptom; no distress indicated; and no impact on function, activity or behaviour

Slightly – evidence of symptom but no significant distress, and no impact on function, activity or behaviour

Moderately – evidence of symptom with moderate distress, and some impact on function, activity or behaviour

Severely – evidence of symptom with significant distress; and significant impact on function, activity or behaviour

Overwhelmingly – evidence of significant and severe distress; overwhelming impact on function, activity or behaviour. The resident is not able to participate or engage in activity and/ or demonstrates marked behavioural distress

How do I rate frequency of symptom or problem (questions 3-8)?

Not at all – no evidence of any symptom or problem in the last seven days

Occasionally – occasional evidence of symptom or problem with no significant impact on function, activity or behaviour

Sometimes – occasional bad days with some impact on function, activity or behaviour

Most of the time – symptom or problem is present often, impacting on function, activity and behaviour most days

Yes, always – symptom is experienced all of the time, always impact on function, activity or behaviour

POS-Dem

www.pos-pal.org

How do I rate time period (questions 9-11)?

Always - no evidence of any distress. Resident always has opportunity to engage when required

Most of the time - may be some brief delay in opportunity but does not cause significant distress

Sometimes – a lack of opportunity on occasional days resulting in a lack of stimulation, lack of engagement and distress

Occasionally – lack of opportunity most days resulting in lack of stimulation, lack of engagement and distress

Not at all – little or no opportunities resulting in lack of stimulation, lack of engagement and distress

How do I use symptom indicators?

We have provided symptom indicators to help you assess the following symptoms:

- Pain
- Mouth and dental problems
- Anxiety
- Depression

You may find it helpful to use these to help identify if a resident has a symptom. Underlining the symptom indicators that the resident demonstrates may help show your assessment to doctors and nurses that you are working with.

POS-Dem

www.pos-pal.org

POS-Dem Assessment

Please write clearly

Person's name:.....

Person's number .....

Date (dd/mm/yyyy):.....

Q1. What have been the person's main problems over the past week?

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*
1.....					
	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
2.....					
	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
3.....					
	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Q2. Please tick one box that best describes how the person has been affected by each of the following symptoms over the past week?

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot assess*
Pain	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Shortness of breath	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weakness or lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

POS-Dem

www.pos-pal.org

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot assess*
Nausea (feeling like you are going to be sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Vomiting (being sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor appetite	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Constipation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Sore or dry mouth	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Drowsiness	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor mobility	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Swallowing Problems	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Dental problems	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weight loss	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Loose bowels	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Skin breakdown	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Residents with cognitive impairment or dementia:						
Delusions	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Hallucinations	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Agitation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Wandering	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please list any other symptoms and tick <u>one box</u> to show how you feel each of these symptoms have <u>affected</u> the person <u>over the past week</u>.

1.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
2.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
3.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

9

POS-Dem Version 2_020315

POS-Dem

www.pos-pal.org

Over the past week:

Q3. Has s/he been feeling anxious or worried?

Not at all	Occasionally	Sometimes	Most of the time	Always	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q4. Have any of his/her family or friends been anxious or worried about the person?

Not at all	Occasionally	Sometimes	Most of the time	Always	Not applicable
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q5. Do you think s/he felt depressed?

Not at all	Occasionally	Sometimes	Most of the time	Always	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q6. Has s/he experienced loss of interest in things or activities s/he would normally enjoy?

Not at all	Occasionally	Sometimes	Most of the time	Always	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q7. Has s/he become distressed by problems with communication?

Not at all	Occasionally	Sometimes	Most of the time	Always	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q8. Do you think that s/he has had poor sleep quality?

Not at all	Occasionally	Sometimes	Most of the time	Always	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q9. Do you think s/he has felt at peace?

Always	Most of the time	Sometimes	Occasionally	Not at all	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q10. Has s/he been able to interact positively with others?

Always	Most of the time	Sometimes	Occasionally	Not at all	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q11. Does s/he have the opportunity to engage in enjoyable or pleasurable activities?

Always	Most of the time	Sometimes	Occasionally	Not at all	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Q12. Has his/her family had as much information as wanted?

Always	Most of the time	Sometimes	Occasionally	Not at all	Cannot assess
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

POS-Dem

www.pos-pal.org

Q13. Have any practical problems resulting from his/her illness been addressed? [such as financial and personal]

Problems addressed/ No problems	*Problems mostly addressed*	*Problems partly addressed*	*Problems hardly addressed*	*Problems not addressed*	*Cannot assess*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please specify all:

1.....

2.....

3.....

Q14. Have any care problems been addressed? [hearing aids, foot care, glasses]

Problems addressed/ No problems	*Problems mostly addressed*	*Problems partly addressed*	*Problems hardly addressed*	*Problems not addressed*	*Cannot assess*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please specify all:

1.....

2.....

3.....

Q15. Are priorities and preferences for care reviewed and documented?

Matters addressed/ No problems	*Matters mostly addressed*	*Matters partly addressed*	*Matters hardly addressed*	*Matters not addressed*	*Cannot assess*
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

IPOS-Dem Version 2.1: Ready for cognitive interviews round 2

The Palliative care Outcome Scale for Dementia - Assessment

POS-DemA

An assessment tool to detect symptoms and problems in care home residents with dementia

Manual and assessment tool

POS-DemA manual and assessment_version 2.1_10062015

POS-DemA

www.pos-pal.org

What is POS-DemA?

POS-DemA is an assessment measure. It is developed to detect and manage symptoms and problems in care home residents, including those with dementia. POS-DemA is a brief form for care staff to complete. It asks care staff to assess and rate the severity of common symptoms and problems. This is done by ticking a choice of boxes from 0 (no concern) to 4 (overwhelming). There is space to write additional symptoms or problems. As people with dementia may be unable to say if they are experiencing a symptom, POS-DemA includes behavioural or observational signs of common symptoms (such as pain and depression) – see pages 13-16. We advise that care staff refer to these when using POS-DemA to improve symptom assessment in those people who have problems communicating verbally.

POS-DemA is designed to be used by staff who provide direct care. Any member of the care staff who knows the person well can use POS-DemA. Clinical training or dementia training is not required.

If you would like more information on how POS-DemA was developed, please see page 17.

What is palliative care?

Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Palliative care provides an extra level of support for patients and their families, whatever their diagnosis. The goal is best quality of life for patients and their families, and includes control of pain and other symptoms, as well as attention to psychological, social and spiritual problems (King's College London 2015)

POS-DemA

www.pos-pal.org

Instructions

Please read this section before using POS-DemA for the first time

Who is POS-DemA for?

POS-DemA is for all older care home residents. It is not just for those at the end of life.

How often should POS-DemA be used with each person?

We recommend that you use POS-DemA when someone first moves into the care home. This is so that problems are identified as soon as possible. These can then be addressed in the care plan. We recommend that POS-DemA is then used monthly or at each care plan review and if you notice a change in the person. This is so that you can assess and monitor any new symptoms or problems in a standardised way. POS-DemA can be used as often as you find helpful.

Who should complete POS-DemA?

Any member of the care staff who provides regular and direct care should complete POS-DemA. Preferably, the staff member who knows the person best. We recommend that the care staff member who has worked with the person the most in the past week completes POS-DemA.

How do I complete POS-DemA?

In all assessments it is best to ask the person directly. This is the best way to find out about problems or symptoms. You can do this as part of your normal care.

However, people with dementia may not be able to tell you when they have a problem. You should complete POS-DemA based on your own observations of the person's behaviour. For example, observing non-verbal signs such as crying out when moving. You should also have discussions with colleagues. Make sure you speak to colleagues who work different shifts. Read case notes especially if you do not have the opportunity to speak to colleagues. Ask family and friends for their opinions. Family and friends may also have their own problems that need addressing.

POS-DemA

www.pos-pal.org

We know that it can be difficult to assess problems in people who have difficulties communicating verbally. We know that many care staff rely on observed behaviour to assess symptoms. To support assessment, we have provided common behaviours that people may show if they experience a symptom. We have provided these for pain (page 13), mouth or dental problems (page 14), anxiety (page 15), and depression (page 16). We strongly suggest that you refer to these when completing the assessment. You can underline the behaviours you have observed in these sections. This will provide more information about your assessment. It could also help explain your assessment to doctors and nurses.

Should POS-DemA replace existing assessments?

POS-DemA should not replace other assessments. POS-DemA aims to assess and monitor symptoms and problems that may be distressing for the person. POS-DemA is NOT a risk assessment. It should NOT be used to replace risk assessments.

How can POS-DemA support the care that I provide?

POS-DemA is designed to help you detect symptoms and other problems that may cause distress. POS-DemA can help you write care plans by identifying these systematically. By discussing POS-DemA with family and friends, you can also get their views and understand their problems.

You can also use POS-DemA to work with doctors and nurses. You can show them the completed POS-DemA to help explain symptoms. The scores on POS-DemA can help you tell doctors and nurses how severely the symptoms affect the person and how these have changed over time.

Used in this way, POS-DemA can support joint working between you, health professionals, family or friends, and residents.

IT IS VERY IMPORTANT THAT YOU TAKE ACTION WHEN YOU DETECT A PROBLEM. This action may depend on the symptom or problem, and its severity. A higher score means a worse symptom or problem. This means that you may have to act **urgently**. You may wish to discuss higher scores

with a senior member of staff. You may need to refer the person for an urgent review with the doctor for severe or overwhelming symptoms or problems.

How do I rate severity (question 2), frequency (questions 3-7) and time period (questions 8-10)?

Sometimes it can be difficult to select an option from the choices. For example, it may be difficult to choose between slight pain and moderate pain. This could be for a number of reasons. For example, it could be because the person has changed a lot over the past week. If you find it difficult to choose an option, please refer to the following descriptions.

How do I rate severity (question 2)?

Not at all - no evidence of any symptom; no distress indicated; and no impact on function, activity or behaviour

Slightly – evidence of symptom but no significant distress, and no impact on function, activity or behaviour

Moderately – evidence of symptom with moderate distress, and some impact on function, activity or behaviour

Severely – evidence of symptom with significant distress; and significant impact on function, activity or behaviour

Overwhelmingly – evidence of significant and severe distress; overwhelming impact on function, activity or behaviour. The resident is not able to participate or engage in activity and/ or demonstrates marked behavioural distress

How do I rate frequency of symptom or problem (questions 3-7)?

Not at all – no evidence of any symptom or problem in the last seven days

Occasionally – occasional evidence of symptom or problem with no significant impact on function, activity or behaviour in the last seven days

Sometimes – occasional bad days with some impact on function, activity or behaviour over the last seven days

Most of the time – symptom or problem is present often, impacting on function, activity and behaviour most days during the last seven days

POS-DemA

www.pos-pal.org

Yes, always – symptom is experienced all of the time, always impact on function, activity or behaviour, throughout the last seven days

How do I rate time period (questions 8-10)?

Always – shows peace, enjoyment, or engagement all the time over the last seven days

Most of the time – mostly at peace and demonstrating enjoyment and engagement over the past seven days

Sometimes – a lack of engagement or withdrawal or some distress on some days over the last seven days

Occasionally – lack of engagement, withdrawal and distress on most days over the last seven days

Not at all – lack of engagement, withdrawal and distress every day throughout the last seven days

POS-DemA

www.pos-pal.org

POS-DemA Assessment

Please write clearly

Person's name:.....

Person's number .....

Date (dd/mm/yyyy):.....

Q1. What have been the person's main problems over the past week? Please consider all problems that the person is experiencing that may cause distress.

1.....

2.....

3.....

Q2. Please tick one box that best describes how the person has been affected by each of the following symptoms over the past week? Please refer to pages 6-7 if you have problems selecting an option.

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot assess*
Pain (see page 13 for pain signs)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Shortness of breath	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weakness or lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Nausea (feeling like s/he is going to be sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Vomiting (being sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

POS-DemA

www.pos-pal.org

	Not at all	Slightly	Moderately	Severely	Over-whelmingly	Cannot assess
Poor appetite	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Constipation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Dental problems (see pages 14-15 for signs)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Sore or dry mouth (see pages 14-15 for signs)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Drowsiness	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor mobility (requires aid or assistance)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Swallowing Problems (e.g. chokes, inhales food or drink, holds food in mouth)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Skin breakdown	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Sleeping problems	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Diarrhoea (loose bowels)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Delusions (Fixed belief that is clearly false e.g. believes others are stealing from him/her'	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

POS-DemA

www.pos-pal.org

	Not at all	Slightly	Moderately	Severely	Over-whelmingly	Cannot assess
Hallucinations (Seeing or hearing things such as animals, people, or objects that are not present'	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Agitation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Wandering	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please list any other symptoms and tick one box to show how you feel each of these symptoms have affected the person over the past week (optional).

1.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
2.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
3.....0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Over the past week:

	Not at all	Occasionally	Sometimes	Most of the time	Always	Cannot assess
Q3. Has s/he been feeling anxious or worried?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q4. Have any of his/her family been anxious or worried about the person	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q5. Do you think s/he felt depressed?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

POS-DemA

www.pos-pal.org

Over the past week:

	Not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Always*	*Cannot assess*
Q6. Has s/he experienced loss of interest in things s/he would normally enjoy?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q7. Has s/he become distressed or frustrated by problems expressing him / herself?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Over the past week:

	Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*	*Cannot assess*
Q8. Do you think s/he felt at peace?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q9. Has s/he been able to interact positively with others?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q10. Can s/he Enjoy or engage in activities appropriate for his/her level of interests and abilities?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

POS-DemA

www.pos-pal.org

Over the past week:

	Problems addressed/ No problems	*Problems mostly addressed*	*Problems partly addressed*	*Problems hardly addressed*	*Problems not addressed*	*Cannot assess*
Q11. Have any practical problems been addressed? [such as hearing aids, foot care, glasses, diet]	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q12. Have priorities and preferences for care both now and for the future been reviewed with family and GP and documented?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

What was the person's last weight and the date s/he was last weighed?

Weight .....kg

Date ...../...../.....

Appendix P. IPOS-Dem Version 3 with instruction manual

The Integrated Palliative care Outcome Scale for Dementia

IPOS-Dem

An assessment to detect and assess symptoms and problems in people with dementia

Manual for use in care homes

IPOS-Dem

Contents

IPOS-Dem

What is IPOS-Dem?

IPOS-Dem is an assessment tool. It is developed to detect and assess symptoms and problems in care home residents, including those with dementia. IPOS-Dem is a brief questionnaire for care staff to complete. It asks care staff to assess and score the severity of common symptoms and problems. This is done by selecting from 0 (no concern) to 4 (overwhelming). There is space to write additional symptoms or problems. People with dementia may be unable to say if they are experiencing a symptom.

IPOS-Dem is designed to be used by staff who provide direct care. Any member of the care staff who knows the person can use IPOS-Dem. Clinical training or dementia training is not required.

If you would like more information on how IPOS-Dem was developed, please see page 15.

What is palliative care?

Palliative care aims relieve suffering and to improve quality of life. This is achieved through quick assessment and treatment of symptoms and problems. Palliative care is not just care in the last days or weeks of life. Palliative care can benefit people throughout the last years of life.

IPOS-Dem

Instructions

Who is IPOS-Dem for?

Older people in care homes, particularly those in the later stages of dementia, are often frail. They often have many physical symptoms. We know that symptoms in people with dementia may not be detected. IPOS-Dem aims to help care staff detect and assess symptoms so they can get more help.

Palliative care is not just care in last days or weeks of life. Palliative care can benefit people throughout the last years of life once cure is no longer possible. IPOS-Dem is therefore for all older care home residents. It is not just for those at the end of life.

How often should IPOS-Dem be used with each person?

We recommend that you use IPOS-Dem when someone first moves into the care home. This is so that problems are identified as soon as possible. These can then be addressed in the care plan. We recommend that IPOS-Dem is then used monthly or at each care plan review and if you notice a change in the person. This is so that you can assess and monitor any new symptoms or problems in a standardised way. IPOS-Dem can be used as often as you find helpful.

Who should complete IPOS-Dem?

Any member of the care staff who provides regular and direct care should complete IPOS-Dem. Preferably, the staff member who knows the person best. We recommend that the care staff member who has worked with the person the most in the past week completes IPOS-Dem.

How do I complete IPOS-Dem?

In all assessments it is best to ask the person directly. This is the best way to find out about problems or symptoms. You can do this as part of your normal care.

However, people with dementia may not be able to tell you when they have a problem. You should complete IPOS-Dem based on your own observations of the person's behaviour. For example, observing non-verbal signs such as crying out when moving. You should also have discussions with colleagues. Make sure you speak to colleagues who work different shifts. Read case notes especially if you do not have the opportunity to speak to colleagues. Ask family and friends for their opinions. Family and friends may also have their own problems that need addressing.

IPOS-Dem

Should IPOS-Dem replace existing assessments?

IPOS-Dem should not replace other assessments. IPOS-Dem aims to help you to assess and monitor symptoms and problems that may be distressing for the person. IPOS-Dem is NOT a risk assessment. It should NOT be used to replace risk assessments.

How can IPOS-Dem support the care that I provide?

IPOS-Dem is designed to help you detect symptoms and other problems that may cause distress. IPOS-Dem can help you write care plans by identifying these systematically. By discussing IPOS-Dem with family and friends, you can also understand their views on the resident's problems.

You can also use IPOS-Dem to work with doctors and nurses. You can show them the completed IPOS-Dem to help explain symptoms. The scores on IPOS-Dem can help you tell doctors and nurses how severely the symptoms affect the person and how these have changed over time.

Used in this way, IPOS-Dem can support joint working between you, health professionals, family or friends, and residents.

IT IS VERY IMPORTANT THAT YOU TAKE ACTION WHEN YOU DETECT A PROBLEM. This action may depend on the symptom or problem, and its severity. A higher score means a worse symptom or problem. This means that you may have to act **urgently**. You may wish to discuss higher scores with a senior member of staff. You may need to refer the person for an urgent review with the doctor for severe or overwhelming symptoms or problems.

IPOS-Dem

IPOS-Dem Assessment

Please write clearly

Person's name:.....

Person's number .....

Date (dd/mm/yyyy):.....

Q1. What have been the person's main problems over the past week?

1.....

2.....

3.....

IPOS-Dem

Q2. Please select one box that best describes how the person has been affected by each of the following symptoms over the past week.

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot assess*
Pain	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Shortness of breath	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Weakness or lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Nausea (feeling like being sick/vomiting)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Vomiting (being sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor appetite	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Constipation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Dental problems or problems with dentures	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Sore or dry mouth	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Drowsiness (sleepiness)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Poor mobility (trouble walking, cannot leave bed, falling)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

IPOS-Dem

	Not at all	*Slightly*	*Moderately*	*Severely*	*Over-whelmingly*	*Cannot assess*
Swallowing problems (e.g. chokes, inhales food or drink, holds food in mouth)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Skin breakdown (redness, skin tearing, pressure damage)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Difficulty communicating	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Sleeping problems	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Diarrhoea	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Hallucinations (seeing or hearing things not present) and/or delusions (fixed false beliefs)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Agitation (restless, irritable, aggressive)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Wandering (as a result of distress or putting person at risk)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Has the person had any other symptoms? Please select one box to show how you feel each of these symptoms have <u>affected</u> the person <u>over the past week</u> (optional).

1.....0	☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
2.....0	☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
3.....0	☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

8

IPOS-Dem

Over the past week:

	Not at all	*Occasionally*	*Sometimes*	*Most of the time*	*Always*	*Cannot assess*
Q3. Has s/he been feeling anxious or worried?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q4. Have any of his/her family been anxious or worried about the person?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q5. Do you think s/he felt depressed?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q5b. Lost interest in things things s/he would normally enjoy?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Please turn over

9

IPOS-Dem

Over the past week:

	Always	*Most of the time*	*Sometimes*	*Occasionally*	*Not at all*	*Cannot assess*
Q6. Do you think s/he felt at peace?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q7. Has s/he been able to interact positively with others (e.g. staff, family, residents)?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q7b. Can s/he enjoy activities appropriate for his/her level of interests and abilities?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐
Q8. Has his/her family had as much information as wanted?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

Over the past week:

	Problems addressed/ No problems	*Problems mostly addressed*	*Problems partly addressed*	*Problems hardly addressed*	*Problems not addressed*	*Cannot assess*
Q9. Have all practical problems been addressed? [e.g. hearing aids, foot care, glasses, diet]	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	☐

What was the person's last weight and the date s/he was last weighed?

Weight .....kg

Date...../...../.....

10